

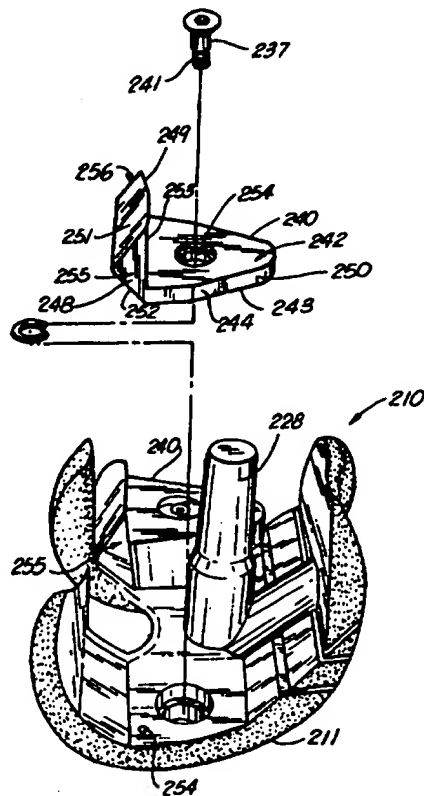
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶: A61F	A2	(11) International Publication Number: WO 96/25123 (43) International Publication Date: 22 August 1996 (22.08.96)
(21) International Application Number: PCT/US96/02127 (22) International Filing Date: 15 February 1996 (15.02.96) (30) Priority Data: 08/389,100 15 February 1995 (15.02.95) US (71) Applicant: SMITH & NEPHEW RICHARDS INC. [US/US]; 1450 Brooks Road, Memphis, TN 38116 (US). (72) Inventors: CARLS, Thomas, A.; 1736 Carruthers Place, Memphis, TN 38112 (US). JOHNSON, Chris, E.; 5030 Woodlark Avenue, Memphis, TN 38117 (US). STEELE, John; Suite 2303, 1050 South Blackhawk, Aurora, CO 80012 (US). VENDRELY, Tim; 2234 Brewer's Landing, Memphis, TN 38104 (US). WHITESIDE, Leo, A.; 3165 McKelvey Road, Bridgeton, MO 63044 (US). NARAGHIAN, Khosrow; 3426 Castleman, Memphis, TN 38118 (US). (74) Agents: KRIEGER, Paul, E. et al.; Pravel, Hewitt, Kimball & Krieger, P.C., 10th floor, 1177 West Loop South, Houston, TX 77027-9095 (US).		(81) Designated States: AU, CA, CN, JP, KR, SG, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>Without international search report and to be republished upon receipt of that report.</i>

(54) Title: TRIAL KNEE PROSTHESIS AND BONE PREPARATION SYSTEM**(57) Abstract**

A trial knee prosthesis suitable for use in knee joint replacement surgery and for revising a previously implanted total knee implant. The trial knee prosthesis comprises at least a trial tibial prosthesis and a trial femoral prosthesis. There is also provided a method for implanting a femoral and a tibial knee prosthesis and instruments for surgically implanting the femoral and tibial prosthesis component using the trial knee as disclosed.



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TRIAL KNEE PROSTHESIS
AND BONE PREPARATION SYSTEM

The present invention relates to orthopedic surgical
5 instruments and surgical methods and more particularly relates to an
improved method and apparatus for installing a knee prosthesis with
instrumentation that allows a surgeon to rotate a tibial trial prosthesis
about the patient's intramedullary canal axis with a lever while the
patient's knee is flexed through a full range of motion and with a
10 corresponding femoral trial prosthesis in place.

The present invention also relates to orthopedic surgical
instruments and surgical methods and particularly relates to an
improved method and apparatus for assisting a surgeon to revise a
15 previously implanted total knee implant. More particularly the present
invention also relates to an improved method and apparatus for
installing a knee prosthesis with modular instrumentation that allows a
surgeon to build a revision femoral trial prosthesis using multiple trial
wedge portions of different size and shape that can be butted to a
20 prosthesis body. This "trial" not only allows the surgeon to evaluate
the proper implant size, but it is also used to assist the surgeon in
preparing the bone for implants and to correctly orient the implants in
different planes.

25 In knee joint replacement surgery, a surgeon typically affixes
two prosthesis components to the patient's femur and tibia. These
replacement components are typically known as the femoral
component and the tibial component.

30 The femoral component is placed on a patient's distal femur
after the surgeon makes a plurality of surgical cuts. One common
type of femoral prosthesis has a J-shape. A femoral prosthesis is

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usually metallic, having a highly polished outer femoral articulating surface.

5 A common type of tibial prosthesis uses a laterally extending tray that is shaped to conform to the patient's proximal tibia after the proximal tibia has been cut transversely by the surgeon. The tibia prosthesis also includes a stem or plug that extends generally perpendicular to the tray and from the center of the tray. The stem is placed in a surgically formed opening that extends into the patient's
10 intramedullary canal from the transverse cut formed on the proximal tibia.

A plastic, polymeric insert is attached to the tibial tray. This insert provides a tibial articulating surface that articulates with the
15 femoral articulating surface as the patient's tibia moves through a full range of motion with respect to the patient's femur.

One of the problems with knee joint replacement surgery is that of accurately fitting the patient. Each patient has a different bone
20 structure and geometry. Even though the surgeon uses x-rays to study a particular patient's anatomy at the knee, the surgeon does not have a perfect appreciation of the patient's anatomy until after the knee has been surgically exposed and the surgeon begins to make cuts on the femur and the tibia.

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Knee prosthetic components are not available in infinite sizes. The surgeon must examine the patient's anatomy, make the requisite surgical cuts and install prosthesis components that fit.

30 A number of prosthetic knee components have been patented. Some relate to femoral components and tibial components. Other

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patents have been issued that relate to cutting instrumentation for preparing the patient's distal femur or proximal tibia to receive a prosthetic knee component as part of knee joint replacement surgery.

5 A number of tibial components have been patented that relate to tibial components having a tray, a plastic insert with articulating surface, and a stem portion that provides initial fixation when the prosthesis is implanted. Other patents have issued that relate to cutting instrumentation for preparing the patient's proximal tibia to
10 receive a tibial prosthetic insert as part of knee joint replacement surgery.

 The Murray patent 4,016,606 discloses a knee prosthesis that includes a tibial component with a tray and with a stem adapted to be
15 received in a longitudinal bore in the patient's femur. The stem has one end that is integral with a depending generally spheroidal surface having generally the same radius as the radius of the spheroidal depression in the insert.

20 In the Chiarizzio patent 4,601,289 there is disclosed a femoral trial prosthesis/rasp assembly used in hip implant surgery. The assembly includes a handle that grips the combination trial prosthesis/rasp in a secure manner by clamping over and locking on to a post on the trial prosthesis/rasp which later serves as a mounting
25 piece for a femoral prosthesis head used in trial reductions.

 A modular tibial prosthesis is disclosed in the Shaw Patent 4,938,769. The Shaw patent discloses a tibial prosthesis for use during a total knee arthroplasty procedure which includes a modular
30 two part tibial component comprising an in-bone anchorage assembly to which is removably attached a tibial tray adapted to receive and

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retain a bearing insert. Removal of the tray permits access to the interface between the bone and anchorage assembly in the event removal or revision are necessary. In preferred embodiments, the invention affords hybrid fixation of the tibial prosthesis in that bone cement for immediate fixation and adaptation for longer term bone ingrowth are featured. Shaw also discusses the use of porous coatings to enhance fixation.

U.S. Patent 4,938,769 issued to James Shaw discloses an end bone anchorage assembly for a tibial prosthesis that includes an axially elongated central stem and a plurality of elongated fixation pegs spaced from the stem. The stem and the pegs have proximal and distal ends. The proximal ends of the stem define an attachment table. A plurality of structural links interconnect the pegs and the stem. Means is provided for removably attaching a tibial tray to the assembly wherein each of the pegs is connected to the stem by the structural link.

A tibial component for a replacement knee prosthesis is disclosed in the Lawes et al. Patent 5,080,675. Lawes discloses a tibial component for a replacement knee prosthesis comprising a tibial tray for connection to a suitably prepared tibia, the tray carrying fixed lateral and medial condylar bearing components. Only the medial component has a shock absorber located beneath it.

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U.S. Patent 5,137,536 issued to Tomihisa Koshino describes a tibial component for an artificial knee joint. The tibial component includes a plate section having an upper surface and a pair of bearing surfaces parts that are adapted to be in sliding contact with a femoral component. A stem portion extends downwardly from a lower surface of the plate section. A pair of blade like members extend obliquely

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and posteriorly from the stem. The plate section has a lower surface with a plurality of elongated grooves for improving affinity with respect to the surrounding bone, the grooves including a first group of grooves and a second set of group of grooves extending
5 perpendicularly to the first group of grooves.

An example of a modular tibial support is seen in the Elias Patent 5,246,459 entitled "Modular Tibial Support Pegs for the Tibial Component of a Prosthetic Knee Replacement System". The Elias
10 Patent discloses a modular tibial support peg operable to secure a tibial component of a knee joint prosthesis to a tibia having a groove. The modular tibial support peg includes a cylindrical body with a ridged outer surface operable to engage the groove in the tibia. The modular tibial support peg further includes a plurality of spikes
15 extending inferiorly from the cylindrical body. The spikes are operable to engage the tibia at the inferior end of the groove.

The Whiteside Patent 4,467,801, entitled "Method And
20 Apparatus For Shaping A Proximal Tibial Surface", provides a method and apparatus for preparing the proximal surface of a tibia to receive a proximal tibial prosthesis employing a reamer/alignment guide which is used to internally locate the central long axis of the tibia and a plateau planar which cooperatively engages with a guide handle
25 attached to the reamer/alignment guide to accomplish the shaping of the proximal tibial surface. The reamer/alignment guide has a rod portion extending into the interior of the tibial shaft whose central long axis corresponds with the central long axis of the tibia. The guide handle is concentric with that rod portion such that the plateau planar
30 assumes the proper alignment with respect to the central long axis of

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the tibia such that the proximal tibial surface is shaped relative to that axis in a simple and accurate manner.

European Patent Application No. 0 122 669 discloses a guide
5 for femoral neck osteotomy that comprises a longitudinal rod having
attaching structure at the lower end thereof for securing the rod to a
femur at the greater trochanter. A transversely extending support arm
is secured to the rod adjacent the lower end thereof, and a guide bar
10 is connected to the support arm. The guide bar has at least one
elongated planar surface disposed at an angle of 45° to the axis of
the rod. In use, the rod is aligned with the long shaft axis of the femur
and attached to the femur at the greater trochanter. The rod is
manipulated until the support arm and the long shaft axis of the tibia
are disposed in the same plane. This procedure properly positions
15 the elongated planar surface of the guide bar whereby an instrument
in engagement with that surface traverses the femoral neck at an
angle of 45° to the long shaft axis of the femur.

Another Whiteside Patent No. 4,474,177 provides a method and
20 apparatus for preparing the distal surface of a femur to receive a distal
femoral prosthesis employing an intramedullary reamer which is used
to internally locate the central long axis of the femur, an
intramedullary alignment guide which is inserted into the space left in
the intramedullary canal upon removal of the reamer and at least one
25 femoral surface modifying instrument which cooperatively engages
with a guide handle attached to the intramedullary alignment guide to
accomplish the shaping of the distal femoral surface. The
intramedullary alignment guide has a rod portion extending into the
femoral intramedullary canal whose central long axis corresponds with
30 the central long axis of the femur. The guide handle is attached to
that rod portion at a preselected angle such that the shaping

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instruments fixed thereto assume the proper alignment with respect to the central long axis of the femur such that the distal femoral surface is shaped relative to that axis in a simple and accurate manner.

- 5 An improved triplanar knee resection system, disclosed in U.S. Patent 4,487,203, provides a system for preparing a knee joint for a prosthesis. The apparatus of the triplanar knee system includes a single guide member for use in resecting the distal femoral condyles, the proximal tibia, and the distal femur. The guide member
- 10 cooperates with a simplified set of instruments, including femur and tibia guide rods, a tibia adaptor, a tibia bar, and a femur bar, for establishing equal flexion and extension gaps and triplanar resections. The method of the triplanar knee system provides a simplified procedure for use by an orthopedic surgeon in properly
- 15 preparing a knee joint for implantation of a prosthesis.

- The Petersen Patent No. 4,567,886 discloses a spacer guide for utilization in total knee surgery for establishing size of prosthesis and position of cuts for total knee replacement surgery includes a
- 20 generally L-shaped base member for attachment to the anterior femoral cortex of a prepared femur with a generally L-shaped adjustable support member adjustably secured to the base support member and a vertically positionable indicator slide having a squaring jig for cooperative engagement and alignment with the cutting head of
- 25 a tibia alignment and resection guide for squaring the tibia and femur and including indicator means for indicating the position of a tibia plateau cut and indicating the size and positioning for a distal femoral cut for indicating the sizing of the both the tibial and femoral
- prostheses.

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The Kenna et al. Patent No. 4,464,729 discloses a prosthetic knee implanted after cutting the femur and tibia with the aid of instruments which include axial alignment guides and a series of cutting jigs.

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A method and apparatus for resecting a distal femoral surface is disclosed in U.S. Patent No. 4,703,751 in which an intramedullary rod is inserted through the distal surface of the femur and along the femoral shaft access, leaving a protruding end; a jig is attached to the protruding end, the jig having a shaft for receiving the rod end and a support plate attached to an end of the shaft and extending parallel to the rod; attaching a reference bar to the shaft, the bar having a pair of opposing flanges and a central opening which receives the shaft therethrough, and adjusting the bar on the shaft such that the flanges contact condylar apices of the femur; fixing the jig relative to the femur; attaching a cutting plate to the jig, the cutting plate having blade guides thereon, pivoting the cutting plate relative to the jig such that the blade guides make a predetermined angle with the rod, and securing the cutting plate to the jig; and inserting a saw blade through the blade guides to make a resection of the distal femoral surface. In the preferred embodiment, the shaft includes a plurality of bores along its length, each sized to receive the rod therethrough so that the distance between the rod and the support plate may be adjusted to accept different sized anterior femur portions. Also in the preferred embodiment, the apparatus includes a plurality of guide bars, each sized to space the blade guides a predetermined distance from the condylar apices.

The Kaufman et al. Patent No. 4,721,104 relates to a surgical apparatus for providing an accurate recess in a distal femoral surface for the intercondylar stabilizing housing of a posterior-stabilized knee

implant prosthesis which apparatus comprises a template having a bottom surface which is adapted to be placed in an aligning relationship with the flat surface of a distal femur which has been partially shaped to receive the femoral component of a posterior-stabilized knee implant prosthesis and a U-shaped slot passing through the template where the slot is of substantially the same size and shape as the outer periphery of the intercondylar stabilizing housing present on the femoral component to be implanted and a drilling means, preferably in the form of an endmill cutter, having a stop means thereon and the drilling means closely engages the sides of the U-shaped slot in the template so that the drilling means can be passed through the U-shaped slot until the stop means contacts a surface of the guide and is then drawn along the slot to create a precisely shaped and aligned recess in the femur for receipt of the intercondylar stabilizing housing. In a more preferred embodiment, the template is composed of a drilling means guide which fits over a femoral trial prosthesis which is used for trial reductions after the drill guide is used and removed.

20 The Russell et al. Patent No. 4,722,330 relates to distal femoral surface shaping guide for mounting on a intramedullary alignment guide which references the central long axis of the femur in shaping the distal femoral surface and a method for shaping the distal femur using the shaping guide. The alignment guide of the present invention is adjustable relative to the surface of the anterior femoral cortex to insure that the anterior aspect of the distal femoral condyles is resected relative to that surface and, preferably, at the same level as that surface. The alignment guide of the present invention provides a main body which remains attached to the intramedullary alignment guide throughout the entire shaping of the distal femur. It thus requires fewer cutting guides and alignment steps than other

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shaping guides while allowing greater accuracy in shaping the distal femur relative to the central long axis of the femur.

An improved tibial cutting jig is disclosed in U.S. Patent No. 4,736,737, provided for use in obtaining accurate tibial resection in the course of a total knee prosthesis implantation procedure. The tibial cutting jig includes a base for sliding reception onto an intramedullary alignment rod preinstalled generally along the longitudinal axis of the tibia. The base includes laterally extending outriggers carrying removable measurement keys of selected size for spacing the base above the tibial plateau by a selected dimension. An anterior saw guide depends from the base and is thus positioned relative to the tibial plateau in accordance with the sizes of the measurement keys.

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The Buechel et al. Patent No. 4,738,253 discloses a guide for a cutting device used to make a surgical cut in a first bone in desired spatial relationship with a pre-existing cut in a second bone is disclosed to include a means for contacting the pre-existing cut to establish a reference for the desired spatial relationship and a body member engaging the means for contacting and including a guide surface for establishing the desired spatial relationship and guiding a surgical cutting tool to cut the first bone in a plane which is not normally inclined with respect to the long axis of the first bone.

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Another Buechel et al. Patent No. 4,738,254 discloses a positioner for positioning a surgical instrument which acts as a guide for a cutting instrument which produces a surgical cut in an anatomical structure; in one embodiment the positioner positions a surgical instrument which acts as a guide for the cutting instrument at a predetermined position with respect to a previously resected surface

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whereby a further resection is made at a predetermined position with respect to the previously resected surface; and in a further embodiment the positioner acts as an adaptor for a surgical instrument which aids in producing surgical sections thereby allowing the surgical instrument to produce surgical cuts at various predetermined positions relative to a previous surgical cut made at one of several levels.

The Dunn et al. Patent No. 4,759,350 provides a system of instruments for shaping the distal femur and proximal tibia surfaces to receive components of a knee prosthesis for knee replacement surgery. The system references the femur intramedullary channel with a femoral alignment guide to prepare the distal femur that, in turn, is a reference for several cutting guides for sequential attachment to the femoral alignment guide and prepared bone surfaces whereby the prepared distal femur is prepared to a flat surface that is perpendicular to the patient's mechanical axis with bone surfaces adjacent thereto sectioned to surfaces that are at right angles to that distal femur surface with chamfers therebetween to receive the femur component of a knee prosthesis. A tibial cutting guide is provided for preparing the proximal tibia that consists of a sleeve, with a tube telescoped therein, the ends thereof including pin arrangements for connecting them into the tibia, between the ankle and near the proximal tibia, an open tube end of the tibial cutting guide to receive a rod telescoped therein that mounts a cutting guide platform and includes a screw arrangement for releasably maintaining the rod and tube together. The cutting guide platform includes a body with a saw guide slot formed therethrough to receive a saw blade to cut across the proximal tibia to form a surface for accommodating a tibial component of the knee prosthesis, the cutting guide platform body further including an arrangement for securing it to the tibia, slightly

below the proximal tibia, and a tibial resection guide for setting a depth of cut across the proximal tibia.

U.S. Patent No. 4,773,407 issued to Petersen discloses a
5 method and instruments for resection of the distal femur. The
instruments include a distal femoral resector and a femoral alignment
guide/rod. The distal femoral resector is designed to be attached to
the distal femur on a plane filed on the anterior femoral cortex. The
distal femoral resector includes a feeler gauge laterally adjustable to
10 adapt to the intercondylar notch of the particular patient and further
includes a rotating rod having openings therethrough for fastening
pins, which rotating rod is designed to facilitate the placement of the
resector on the anterior femoral cortex in a flush manner. The femoral
alignment guide/rod includes a plate insertable within a slot in the
15 resector designed for the insertion of the cutting tool and further
includes a pivotable rod which may be utilized to align the resector
with the mechanical axis of the leg. The rod may then be pivoted to a
position facilitating the insertion of a fastening pin through the
resector. The method of operation using these instruments is also
20 disclosed.

U.S. Patent No. 4,892,093 issued to Zarnowski et al. discloses a
cutting guide for guiding a saw blade during the preparation of a
femur for the implant of the femoral component of a knee prosthesis
25 includes guide surfaces for enabling the cutting of all four of the
anterior femoral cut, the posterior femoral cut, the anterior chamfer
and the posterior chamfer, fully and completely, with certitude and
accuracy, while the cutting guide remains located and secured to the
femur in a single position on a transverse surface located along the
30 distal femur.

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The Dale et al. U.S. Patent No. 4,893,619 discloses a device for guiding an osteotomy to be performed on the proximal end of a humerus that has a proximal saw guide alignable on a selected surface of the proximal end of the humerus for defining a saw line
5 thereon; a radial arm connecting the saw guide to a distal mechanism for stably aligning the saw guide, the distal alignment mechanism has a pair of opposing lateral and medial epicondyle arms pivotally engagable with the lateral and medial sides of the distal end of the humerus, the epicondyle arms being pivotally mounted in a distal
10 cross arm, the distal end of the radial arm being slidably mounted in the cross arm for distal to proximal slidable movement therein; the proximal end of the radial arm being rotatably connected to the saw guide through a proximal guide bar; the radial arm being supported above the humerus by the proximal guide bar and the epicondyle
15 arms.

U.S. Patent No. 4,907,578 relates to an improved method and instruments for a resection of the distal femur. The parent application discloses a femoral alignment guide/rod including a plate insertable
20 within a guide slot in the resector which is also used for the guided insertion of a cutting tool. The present invention improves upon this structure by providing an auxiliary attachment member on the resector allowing attachment of a new femoral alignment guide/rod on the resector housing proximal to the cutting tool guide slot, which new
25 guide/rod allows easier access to various resector components. In a further aspect, structure is provided allowing the use of the resector with an intramedullary rod to increase accuracy. In this aspect, a gauge is incorporated in the resector which allows compensation for the angle between the mechanical axis of the leg and the longitudinal
30 extent of the internal cavity of the femur while also allowing

compensation or correction for specific anatomical conditions such as, for example, valgus correction.

The Whiteside et al. U.S. Patent No. 4,935,023 relates to a distal femoral surface shaping guide for mounting on an intramedullary alignment which references the central long axis of the femur in shaping the distal femoral surface and a method for shaping the distal femur using that shaping guide with particular applicability for shaping one condyle for attachment of a unicondylar prosthesis. The alignment guide of the present invention is adjustable relative to the surface of the condyle to insure that the distal femoral condyle is resected relative to that surface. The alignment guide of the present invention utilized visual sighting studs and provides a main body which remains attached to the intramedullary alignment guide throughout the entire shaping of the distal femur.

The Bowman et al. U.S. Patent No. 4,952,213 discloses an apparatus for placing a bone cutting saw cutting guide adjacent a proximal surface of a human tibia bone having an elongated rod inserted into the tibia for clampingly supporting a rotating bar on the central longitudinal axis of the tibia bone. The bar being extended from the rod and connected to a pivot device which in turn is connected to a support arm that holds a saw cutting guide against a proximal portion of the tibia bone. The rotation angle of the rod determining the medial-lateral inclination of the saw cutting guide and the pivot device determining the anterior-posterior inclination of the saw cutting guide. The support arm is adjustable in length to determine the height of the saw cutting guide.

The Dunn et al. U.S. Patent No. 4,959,066 provides an osteotomy guide assembly for femoral neck osteotomy and includes a

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saddle locator assembly and a saw guide attachment. The saddle locator assembly includes a barrel-shaped locating device that locates the saddle region of the proximal femur. The barrel further includes a transverse support bar extending from the barrel. The barrel is

5 positioned over an intramedullary shaft which is temporarily positioned in and extends from the medullary canal of the femur. A saw guide is used in conjunction with a saddle locator assembly. The saw guide is attached to the support bar by a single locking means which provides for positional adjustment of the saw guide relative to the support bar in

10 two directions, including adjustment in the anterior-posterior direction along the transverse support bar and axially along the femur via a post which extends from the saw guide.

The Whiteside et al. U.S. Patent No. 5,002,545 provides a

15 shaping guide to permit accurate shaping of the tibial plateau while saving the anterior cruciate ligament. An alignment rod is located anterior to the anterior cruciate ligament and along the anterior cortex of the intramedullary canal of the tibia provides points of reference for all shaping operations. The shaping guide of the present invention is

20 adjustable with respect to the handle portion of the rod so that the amount of resection of the tibial plateau can be controlled readily by the surgeon by raising or lowering of the cutting guide surfaces for resection of the tibia.

25 The Mikhail et al. U.S. Patent No. 5,108,405 discloses a system for performing hip prosthesis revision surgery includes a trial femoral component having a passageway which, upon insertion in the cavity left after removal of the original prosthesis, provides guide means for drilling a channel to receive a guide wire which, upon

30 removal of the trial femoral component, serves as guide means for progressively larger reamers.

The present invention provides an improved method and apparatus for implanting femoral and tibial prosthesis components. Further the present invention provides an improved method and apparatus for implanting revision femoral and tibial prosthesis components.

Using the method and apparatus of the present invention, the surgeon can build a custom "trial" tibial prosthesis to fit the patient's anatomy during revision surgery.

The surgeon first forms a plurality of cuts on the patient's distal femur and fits a femoral trial prosthesis to the surgically prepared distal femur. The femoral trial prosthesis has an articulating surface for engaging a corresponding surface of a tibial prosthesis. The femoral trial also has a non-articulating surface that fits the patient's distal femur at the surgical cuts.

The surgeon forms a transverse cut on the patient's proximal tibia. A tibial trial prosthesis is then assembled from a plurality of components of different shapes and sizes. The tibial trial prosthesis is formed of a trial tibial stem, a trial tibial tray or plate and a trial plastic insert.

In the method of the present invention, a plurality of trays, a plurality of stems, and a plurality of plastic inserts are provided so that the surgeon can custom construct a trial prosthesis with these plurality of trial tibial prosthesis components.

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Each of the plastic inserts has a tibial articulating surface that articulates with the femoral articulating surface of the trial femoral prosthesis.

5 During the surgery, the surgeon can place the femoral articulating surface against the selected tibial trial prosthesis articulating surface so that fit can be viewed before the actual prosthesis components (i.e. tibial and femoral) are implanted. The surgeon can then move the patient's knee joint through a full range of
10 motion during which the femoral and tibial articulating surfaces of the corresponding trial prosthesis components articulate with each other. With the present invention, the surgeon can adjust the relative rotational positions of these trial components before the final positions are fixed.

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 An instrument (preferably a lever with a handle) is provided for rotating the tibial trial prosthesis about its trial stem so that articulation of the femoral trial prosthesis and the tibial trial prosthesis can be observed. The surgeon can observe the fit between the trial tibial and
20 trial femoral prosthesis as the surgeon moves the patient's knee through a full range of motion, and as the surgeon rotates the trial prosthesis into different rotational positions to obtain the best fit.

 Using the method and apparatus of the present invention, the
25 surgeon can build a custom "trial" tibial prosthesis to fit the patient's anatomy and then exactly position the tibial trial prosthesis in a desired rotational position after repeatedly rotating the knee through a full range of motion. In using the method of the present invention, an optimum fit is obtained. This method obtains correct orientation of the
30 knee prosthesis through a full range of motion.

Once the surgeon determines that correct orientation of the components, the surgeon can pin both the femoral trial prosthesis and the tibial trial prosthesis to the underlying bone tissue.

5 The femoral trial prosthesis has openings that allow the surgeon to drill into the underlying tissue. Those openings receive pegs of the final actual femoral prosthesis component after the trial prosthesis is removed. The surgeon rotates the tibial trial prosthesis until it is in an optimum position. The surgeon then pins the tibial trial
10 prosthesis in position. The surgeon can remove the articular insert trial exposing the tibial prep-plate. The surgeon then marks the tibia below the alignment marks on the tibial prep-plate. When using a non-porous implant, the surgeon can remove the articular plastic insert trial and prepare for the distal fins on the implant using an
15 appropriately sized fin punch. If a long stem is desired, the surgeon can then ream up to the stem diameter.

The surgeon places the tibial implant using marks that were made on the tibia when the trial prosthesis was in position, or using the cut
20 made by the fin punch. The fin punch is "stepped" to correspond to different prosthesis sizes. The tibial prosthesis is installed using a tibial impactor to seat the tibial implant on the proximal tibia. The surgeon can use screws or cement to fasten the final selected tibial component to the proximal tibia.

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According to the present invention there is provided a trial knee prosthesis comprising at least;

(a) a femoral trial prosthesis;

(b) a tibial trial prosthesis having a periphery with an open
30 ended socket at the periphery and

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(c) a handle for manipulating the femoral trial prosthesis and tibial trial prosthesis relative to one another.

- Further according to the present invention there is provided a
- 5 trial knee prosthesis comprising:
- a) a femoral trial prosthesis;
 - b) a tibial trial prosthesis having a periphery with an open ended socket at the periphery;
 - c) a handle for manipulating the femoral trial prosthesis and
 - 10 tibial trial prosthesis relative to one another; and
 - d) said handle being slideably attachable to the tibial trial prostheses at the socket, said handle comprising in part a tab member that closely fits within the socket of the tibial trial prosthesis, and wherein the tab member and socket are correspondly sized and
 - 15 shaped .

Further the trial femoral prosthesis may comprise a metallic trial member having a condylar articulating surface and a non-articulating surface adapted to fit the patient's distal femur, and where the tibial

20 trial prosthesis may comprise a trial tibial tray and a plastic trial articular insert having an articulating surface.

The trial knee prosthesis as herein before described further comprises an elongated linear socket carried by the trial tibial

25 prosthesis for receiving one end portion of the handle to define therewith a sliding removable connection.

The trial tibia prosthesis may comprise the following

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(i) a plastic tibial trial prosthesis articular insert having the socket, and wherein the handle forms a connection with the plastic insert at the socket,

5 (ii) a trial tibial tray having proximal and distal end portions and a tibial articular insert that fits the proximal end portion of the tray,

(iii) a trial tibial tray that fits the patient's proximal tibia and a plastic articular insert that fits the trial tibial tray and wherein the
10 handle forms a sliding connection with the articular insert. The connection between the handle and the insert may be a removable connection that is positioned at the interface between the tray and insert.

15 Further the removable connection may include a socket that is positioned at the interface between the tray and the insert, and the socket is positioned so that the handle enables the surgeon to pry the insert and tray apart when a portion of the handle is placed within the socket.

20

Additionally the handle may be an elongated linear handle having first and second end portions, the second end portion having means for forming a connection with the tibial trial prosthesis, said connection being a slidable connection that allows the user to slide
25 the handle into the tibial trial insert for forming a connection with the tibial trial and for removing the tibial trial by pulling on the handle.

Further there may be a manipulating tab portion carried by one end portion of the handle for forming a connection with one of the trial
30 prosthesis, said tab having a smaller cross-sectional area than the cross-sectional area of a majority of the handle.

In another embodiment of the present invention there is provided a trial knee prosthesis for articulating with a patient's femoral condylar articulating surface comprising;

- 5 a) a tibial trial prosthesis that includes a metallic trial tibial tray with a stem that fits the patient's intramedullary canal and a plastic articular insert that is connectable to the tray, the insert having an articulating surface for receiving and articulating with a patient's correspondingly shaped femoral condylar articulating surface;
- 10 b) a handle for manipulating the trial tibial prosthesis, said handle having means for forming a detachable connection with the tibial trial prosthesis;
- c) said tibial trial prosthesis and said handle being rotationally movable together, independently of said femoral articulating surface,
- 15 for enabling a surgeon to use the handle to selectively position the trial tibial prosthesis in a desired rotational position relative to the femoral condylar articulating surface.

Said handle may comprise a gripping portion that can be

20 grasped by the surgeon and a tab position that engages the tibial trial prosthesis.

Further the handle can form a connection with the articular insert, and the handle can remove the insert from the tray while the

25 tray remains implanted on the patient's proximal tibia.

The detachable connection between the handle and the trial prosthesis may be a sliding connection.

30 The trial knee prosthesis as hereinbefore described may further comprise a femoral trial prosthesis that has a femoral articulating

22

surface that engages the tibial articulating surface, and additionally the femoral trial prosthesis may have a pair of condylar articulating surfaces and the tibial trial prosthesis may have a correspondingly shaped articulating surface.

5

In a further embodiment of the invention there is provided a knee trial prosthesis for attachment to a patient's long bone during knee joint replacement surgery comprising:

- 10 a) a trial prep member having means for attaching the prep member to a long bone adjacent the patient's knee joint, the prep member providing a trial articulating surface;
- b) an elongated trial stem that fits the patient's long bone intramedullary canal;
- c) a trial stem taper that is removably attachable to the prep
- 15 plate member; and
- d) a trial stem coupler that forms a connection between the trial stem taper and the trial stem, said coupler comprising a smaller diameter section adapted to form a connection with the trial stem and a larger diameter section adapted to form a connection with the trial
- 20 stem taper, said larger diameter section providing a shaped connecting surface that forms a connection with a correspondingly-shaped connecting surface of the trial stem taper.

The coupler comprises a generally cylindrically-shaped body

25 having a smaller diameter cylindrical section and a larger diameter cylindrical section, and preferably comprises an externally threaded smaller diameter section and a non-threaded larger diameter section having a socket, said socket being sized and shaped to form a connection with the trial stem taper, said stem forming an attachment

30 with said coupler at the threaded section of the coupler.

23

The prep plate tray provides a central opening, and the trial stem taper forms a connection to the prep plate tray at the central opening, wherein the prep plate member may also have a V-shaped notch that communicates with the central opening.

5

In a further embodiment there are at least a pair of said couplers, one of said couplers having a central longitudinal axis and a longitudinally extending socket uniformly disposed about said axis, and or at least one socket having a socket axis that is angled with reference to the coupler axis.

10

Further coupler may have a frustroconically-shaped socket and the trial stem taper has a corresponding frustroconically-shaped projecting portion that forms a taper-lock fit with the socket of the coupler.

15

In a preferred embodiment the trial taper, coupler, and trial stem are of a generally uniform external diameter upon assembly, and preferably the trial stem, coupler, and trial taper are each generally cylindrically shaped.

20

The stem may have a connecting end portion that forms a connection with the coupler, said end portion having a socket for receiving a projecting portion of the coupler.

25

Said socket is internally threaded and wherein said coupler provides an externally threaded section that forms a connection with the threaded portion of the socket.

30

In a further embodiment of the present invention there is provided a trial tibial prosthesis comprising:

a) a prep plate tray;

24

- b) an elongated trial stem;
- c) a trial stem taper that is attachable to the prep plate tray;

and

- d) a trial stem coupler that forms a connection between the
5 trial stem taper and the trial stem, said coupler comprising a smaller
diameter section adapted to form a connection with the trial stem and
a larger diameter section adapted to form a connection with the trial
stem taper, said larger diameter section providing a shaped
connecting surface that forms a connection with a correspondingly-
10 shaped surface of the trial stem taper.

Said coupler may comprise a generally cylindrically-shaped
body having a smaller diameter cylindrical section and a larger
diameter cylindrical section, and the coupler may comprise an
15 externally threaded smaller diameter section and a non-threaded
larger diameter section having a socket, said socket being sized and
shaped to form a connection with the trial stem taper.

The prep plate tray can provide a central opening, and the trial
20 stem taper forms a connection to the prep plate tray at the opening.
Further the prep plate tray may have a V-shaped notch that
communicates with the central opening.

In yet another embodiment there are at least a pair of said
25 couplers, one of said couplers having a central longitudinal axis, a
socket uniformly disposed about said axis, and or a socket having a
socket axis that is angled with reference to the coupler axis.

Further the coupler may have a frustroconically-shaped socket
30 and the trial stem taper has a corresponding frustroconically-shaped

25

projecting portion that forms a taper-lock fit with the socket of the coupler.

5 In a preferred embodiment the assembled trial taper, coupler, and trial stem are of a generally uniform external diameter upon assembly, and preferably the trial stem, coupler, and trial taper are generally cylindrically shaped.

10 The stem may have connecting end portion that forms a connection with the coupler, said end portion having a socket for receiving a projecting portion of the coupler.

Said socket is internally threaded and wherein said coupler provides an externally threaded section that forms a connection with the threaded portion of the socket.

15

The femoral trial prosthesis has connections that allow the surgeon to fit wedge members to the prosthesis body.

20 The present invention provides instrumentation that assists a surgeon in a revision total knee case that has been previously implanted. The present invention can be used to solve a problem of loosening or pain or other like medical conditions.

25 As part of the method of the present invention, the surgeon removes the previous implant to expose the patient's bone tissue. In a revision case, the remaining bone has often degraded or been mechanically eroded.

30 With the apparatus of the present invention, the surgeon can not only shape the patient's bone to fit a knee implant but also uses the

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apparatus of the present invention to "trial" for the actual implant that would be put on that patient's knee as part of the revision surgery.

The apparatus of the present invention includes a prosthesis
5 body that is generally J-shaped having a pair of condylar articulating surfaces including posterior and distal condylar articulating surfaces with a space therebetween. An anterior articulating surface is also provided on the trial body. The proximal side of the trial prosthesis body has a plurality of flat intersecting surfaces. A plurality of wedge
10 members of different size and shape can be attached to the proximal, non-articulating portion of the trial implant body. If the surgeon needs to place a particular wedge in order to accommodate for loss of bone for example, the surgeon would first place a wedge of selected size and shape on the trial prosthesis body. If that particular wedge fits
15 properly, the surgeon would put the corresponding wedge on the final implant. The surgeon could implant the femoral component without any wedges if there was no need to fill in a recess or gap where bone had eroded. A surgeon could also put a wedge on either the medial or lateral side of the trial prosthesis and (the final implant) or the
20 surgeon could have wedges on both sides.

The trial wedges can have different thicknesses. This allows the surgeon to pick the particular trial wedge that allows for the best fit.

25 Each wedge trial can provide a cutting edge. The femoral trial prosthesis itself can also have a cutting edge. Often, the patient's bone will not correctly match the trial implant before the surgeon places the trial implant on the patient's bone. As the surgeon selects from a group of trial prosthesis bodies, one is selected that will
30 actually be slightly smaller than the thickness of remaining bone. As the surgeon drives the trial onto the patient's distal femur, the cutting

27

edges will actually remove bone in the exact places that it needs to be removed in order for the implant to fit snugly. Those cutting edges will cut bone as the trial is placed onto the patient's distal femur. In actual practice, there will not be an enormous amount of bone removed as

5 the distal femur is already cut from the previous implant. The trial implant and its cutting surface simply removes a small bit of bone tissue so as to provide a snug fit.

The trial prosthesis body provides cutting guide slots that are on

10 the anterior and/or posterior portion of the trial. These cutting guide slots allow the surgeon to prepare the distal femur if one or more wedges is to be used. During surgery, the surgeon first places the femoral trial on the patient's distal femur without any wedges being attached. If the femoral component does not seat properly, such as

15 due to extra bone in the anterior chamfer portion, the surgeon can place a saw blade in the anterior chamfer slots in the femoral trial. The surgeon could remove some bone allowing the femoral component to seat properly. If there are some gaps where the wedges might be, the surgeon could use a saw blade into either a

20 large or small slot that is parallel to the non-articulating surface that receives the trial wedge. These cutting guide surfaces are generally parallel and allow the surgeon to remove bone so when the particular selected wedge trial is placed on the trial prosthesis, it will be perfectly fitted. The surgeon uses the slots to "clean up" the bone on the distal

25 femur if it is not perfectly matching up with the selected implant.

The thickness of each wedge should match the corresponding slot that is selected by the surgeon for cutting. The cuts can be made on the patient's distal femur using the cutting guide slots on the trial

30 prosthesis. Typically, a vibrating saw such as a sagittal saw can be used. An osteotome can also be used.

In another embodiment of the present invention there is provided a trial femoral prosthesis for use in knee joint replacement surgery comprising:

5 a) a trial prosthesis body having a distal articulating surface and a proximal non-articulating surface, said articulating surface including medial and lateral condylar portions;

 b) a stem member that extends from the non-articulating surface;

10 c) a trial insert that is connectable to the trial prosthesis body at the non-articulating surface on either the medial or lateral side of the trial prosthesis;

 d) a cutting surface for cutting the patient's distal femur during a placement of the trial prosthesis body on the patient's distal femur.

15

Said non-articulating surface may include;

(i) multiple intersecting flat surfaces;

(ii) a transverse surface that intersects the patient's femoral intramedullary axis at a generally transverse angle, and a pair of
20 generally parallel anterior and posterior surfaces, and wherein the stem generally tracks the patient's intramedullary axis;

(iii) a posterior non-articulating surface and the cutting surface communicates with the posterior non-articulating surface.

(iv) an anterior non-articulating surface and the cutting surface
25 communicates with the anterior non-articulating surface.

Preferably the cutting surface extends along a medial to lateral line, and, most preferably the cutting surface is an anterior cutting surface that extends along a medial to lateral line.

30

29

Preferably the trial prosthesis body is generally J-shaped.

Further the trial prosthesis body and trial insert may have corresponding mating surfaces that abut upon assembly of the trial insert to the trial body.

5

The trial femoral prosthesis may further comprise a plurality of cutting guide slots that extend through the trial body, each slot communicating with the articulating surface and the non-articulating surface. Said cutting guide slots include opposed, spaced apart

10 medial and lateral cutting guide slots, and where the cutting guide slots may each define a plane, preferably wherein at least two of the planes are parallel.

In a further embodiment there is provided a trial femoral

15 prosthesis wherein one of the flat surfaces is an anterior chamfer non-articulating surface and the prosthesis body has a thickened portion on the anterior chamfer non-articulating surface that extends from a position adjacent the stem toward the anterior non-articulating surface.

20

There may be five non-articulating surfaces including a distal surface, an anterior surface, a posterior surface, an anterior chamfer surface and a posterior chamfer surface.

25 Further there may be a plurality of cutting guide slots that extend through the trial body, each slot communicating with the articulating surface and a non-articulating surface. Preferably one of the cutting guide slots is parallel to the anterior chamfer surface, and more preferably there are two spaced apart cutting guide slots including
30 medial and lateral slots that are parallel to the anterior chamfer surface.

Preferably one of the cutting guide slots is parallel to the posterior chamfer surface, and most preferably there are two spaced apart cutting guide slots including medial and lateral slots that are parallel to the posterior chamfer surface.

Preferably one of the cutting guide slots is parallel to the distal non-articulating surface, and most preferably there are two parallel cutting guide slots, each parallel to the distal non-articulating surface.

Further there may be a plurality of cutting guide slots that are parallel to the distal non-articulating surface at least one being medial and at least one being lateral, and wherein at least two of said cutting guide slots are parallel. Preferably there is in addition a cutting guide slot that is generally parallel to the anterior chamfer surface.

According to the present invention there is provided a trial femoral prosthesis for use in knee joint replacement surgery comprising:

- a) a trial prosthesis body having a distal articulating surface and a proximal non-articulating surface, said articulating surface including medial and lateral condylar portions, said distal non-articulating surface including a plurality of flat intersecting surfaces that include distal, anterior chamfer and posterior chamfer surface;
- b) a wedge trial insert that is connectable to the trial prosthesis body at the proximal non-articulating surface and extending toward the anterior and posterior chamfer surfaces;
- c) a plurality of cutting guide slots that extend through the trial body, each slot communicating with the articulating surface and the non-articulating surface.

31

The cutting guide slots may include;

(i) at least one chamfer cutting slot that is parallel to the anterior chamfer surface,

5 (ii) at least one slot for cutting the distal femur to accommodate the trial wedge,

(iii) at least one chamfer cutting slot that is parallel to the posterior chamfer surface.

(iv) at least one posterior slot for cutting the distal femur to accommodate the trial wedge,

10 (v) a pair of slots that define generally parallel planes.

The trial femoral prosthesis further may comprise disconnectable connection means for connection of a selected wedge insert to the femoral trial body during surgery.

15

The trial femoral prosthesis further may comprise cutting edge means on the trial femoral prosthesis body for cutting the patient's distal femur during placement of the trial prosthesis body on the distal femur, and may comprise cutting edge means on the trial wedge insert for cutting the patient's distal femur during placement of the trial prosthesis body and the wedge connected thereto on the distal femur. In addition the trial femoral prosthesis may comprise cutting surfaces on both the trial femoral prosthesis body and the trial femoral wedge for cutting the patient's distal femur during surgical placement of the trial prosthesis body on the distal femur.

20
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The wedge trial and trial body each provide planar non-articulating surfaces that abut upon assembly of a trial wedge to the trial body, and the trial wedge has a first flat surface that fits to the prosthesis body and a second flat surface that fits the patient's surgically prepared distal femur.

30

Preferably the second flat surface is generally parallel to a non-articulating flat surface on the trial body.

5 According to the present invention there is also provided a trial femoral prosthesis for use in knee joint replacement surgery comprising:

 a) a trial prosthesis body having a distal articulating surface and a proximal non-articulating surface, said articulating surface including
10 medial and lateral condylar portions, said proximal non-articulating surface including a plurality of flat intersecting surfaces that include distal, anterior chamfer and posterior chamfer surfaces;

 b) a trial insert that is connectable to the trial prosthesis body at the proximal non-articulating surface and extending along a path
15 spanning between the anterior and posterior chamfer surfaces;

 c) a plurality of cutting guide slots that extend through the trial body along a line that extends along an anterior to posterior line, each slot communicating with the articulating surface and the non-articulating surface; and

20 d) each of said cutting guide slots comprised of parallel flat surface that each define a plane.

Said trial prosthesis may further comprise a final implant for replacing the trial implant, wherein the geometry of the trial prosthesis
25 simulates the size of the implant selected by the surgeon.

Preferably there are a plurality of inserts of different sizes and or, a plurality of inserts of different shapes.

30 Preferably at least one of the slots forms an acute angle with an anterior/posterior line.

Further one of the cutting guide slots is an osteotome track, preferably an osteotome track for cutting the posterior chamfer cut.

- 5 According to the present invention there is also provided a method of implanting a femoral and tibial knee prosthesis components comprising the steps of:
- a) forming a plurality of surgical cuts on the patient's distal femur;
 - 10 b) fitting a femoral trial prosthesis to the surgically prepared distal femur, the femoral trial prosthesis having a femoral articulating surface and a non-articulating surface that fits the patient's distal femur at the surgical cuts;
 - c) forming a transverse cut on the patient's proximal tibia;
 - 15 d) placing a tibial trial prosthesis on the patient's proximal tibia, said tibial trial prosthesis including a tibial stem that fits the patient's intramedullary canal, a metallic tibial tray, and a plastic trial insert that fits the tibial tray said plastic insert having a tibial articulating surface that articulates with the femoral articulating surface;
 - 20 e) placing the femoral articulating surface against the tibial articulating surface during the surgical;
 - f) moving the patient's tibia through a range of motion during which the femoral and tibial articulating surfaces articulate with each other;
 - 25 g) rotating the tibial trial prosthesis about its stem with an instrument that engages the plastic insert so that the instrument can be used to remove the plastic insert for replacement with another insert of a different size;
 - h) wherein articulation of the femoral trial prosthesis and tibial
 - 30 trial prosthesis in step "g" can be observed by the surgeon during the surgical procedure when:

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1) the patient's tibia is moved through a range of motion relative to the patient's femur; and

2) the trial tibial prosthesis is moved into different rotational trial positions.

5

The method may further comprise the step between steps "g" and "h" of attaching a lever to the trial tibial prosthesis plastic insert for rotating the trial tibial prosthesis about its stem, and preferably the step of forming a quick disconnect attachment between the lever and trial prosthesis.

10

Further, step "a" may comprise forming surgical cuts of the following types;

(i) on the distal femur that include at least anterior and posterior cuts that are generally parallel,

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(ii) on the distal femur that include anterior and posterior cuts and a distal cut,

(iii) a distal cut generally perpendicular to the anterior and posterior cuts,

20

(iv) a distal cut generally perpendicular to the anterior and posterior cuts and chamfer cuts extending respectively between the distal cut and the anterior and posterior cuts, forming an acute angle with the distal cut,

(v) or a mixture thereof.

25

Additionally the step between steps "g" and "h" may comprise of attaching an instrument to a slot on the plastic implant of the tibial prosthesis that enables the surgeon to manipulate the trial tibial prosthesis during an articulation of the tibial and femoral articulating surfaces and while the surgeon moves the tibia through a range of motion with respect to the femur.

30

Furthermore in step "d" the trial prosthesis may include a plurality of interchangeable tibial trays and a plurality of tibial stems and further comprising the step of sizing a trial tibial prosthesis by
5 assembling a selected of the trays to fit the patient's surgically prepared proximal tibial and a selected stem to fit the patient's tibial intramedullary canal.

According to the present invention there is provided a further
10 method of implanting a knee implant that includes corresponding femoral and tibial knee prosthesis components comprising the steps of:

- a) forming a plurality of surgical cuts on the patient's distal femur;
- 15 b) fitting a femoral trial prosthesis to the surgically prepared distal femur, the trial prosthesis having a femoral articulating surface;
- c) forming a transverse cut on the patient's proximal tibia;
- d) building a tibial trial prosthesis for placement on the patient's proximal tibia, said tibial trial prosthesis being constructed from a
20 plurality of trays, stems and inserts including a selected tibial stem that fits the patient's intramedullary canal, a selected metallic tibial tray, and a selected plastic trial insert having a tibial articulating surface;
- e) placing the trial tibial prosthesis on the patient's proximal
25 tibia;
- f) placing the femoral articulating surface against the tibial articulating surface;
- g) attaching a lever to the plastic insert;
- h) moving the patient's tibia through a range of motion during
30 which the trial femoral and trial tibial articulating surfaces articulate with each other;

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i) rotating the tibial trial prosthesis about its stem so that articulation of the femoral trial prosthesis and tibial trial prosthesis can be obtained by the surgeon during the surgical procedure when:

- 1) the patient's tibia is moved through a range of motion; and
- 5 2) the trial tibial prosthesis is moved into different rotational trial positions.

The method may further comprise the step between steps "g" and "h" of attaching the lever instrument to a slot on the trial tibial prosthesis insert for enabling the surgeon to rotate the trial tibial prosthesis about its stem. Further the method may comprise the step between steps "g" and "h" of attaching a lever with a handle to the plastic implant of the tibial prosthesis, and or the step of forming a guide disconnect attachment between the lever and trial prosthesis.

15

Further step "a" may comprise forming surgical cuts on the distal femur that include anterior and posterior cuts and a distal cut, wherein the distal cut may be generally perpendicular to the anterior and posterior cuts and chamfer cuts extending respectively between the distal cut and the anterior and posterior cuts.

20

The apparatus may further comprise guide means for installing threaded fasteners through the tibial tray after the trial prosthesis is removed, said guide means comprising a body having multiply bores therethrough at differing angles with a common exit portion .

25

According to the present invention there is also provided a tibial cutting instrument for preparing a patient's proximal tibia to receive a trial knee prosthesis comprising:

30

- a) cutting block means for preparing the proximal tibia with a transverse surgical cut;

37

b) trial prosthesis means that can be surgically implanted to the proximal tibia, said prosthesis including plurality of trays of different sizes, a plurality of stems of different sizes that are each connectable to a plurality of the trays and a plurality of plastic liners that fit the

5 trays; and

c) means, forming a connection with the plastic liner, for rotating the prosthesis means after implantation.

For a further understanding of the nature and objects of the present invention, reference should be had to the following detailed description, taken in conjunction with the accompanying drawings, in which like parts are given like reference numerals, and wherein:

FIGURE 1 is bottom view of the tibial prep-plate portion of the preferred embodiment of the apparatus of the present invention;

FIGURE 2 is a top view of the tibial prep-plate portion of the preferred embodiment of the apparatus of the present invention;

FIGURE 3 is a perspective view of the articular insert trial portion of the preferred embodiment of the apparatus of the present invention;

FIGURE 4 is a bottom view of the articular insert trial portion of the preferred embodiment of the apparatus of the present invention;

FIGURE 5 is a perspective view of the articular insert trial rotation handle portion of the preferred embodiment of the apparatus of the present invention;

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FIGURE 6 is a perspective view of the stem plug portion of the tibial trial insert portion of the preferred embodiment of the apparatus of the present invention;

5 FIGURE 6A is a top view of the plug of Figure 6;

FIGURE 6B is a bottom view of the plug of Figure 6;

10 FIGURE 7 is a schematic perspective view illustrating the trial tibial prosthesis and the trial rotation handle portions of the preferred embodiment of the apparatus of the present invention;

15 FIGURE 8 is a schematic perspective view illustrating a resection of the patella femoral groove, cutting along the medial and lateral sides of the femoral trial;

20 FIGURE 9 illustrates the trial femoral prosthesis and the trial tibial prosthesis installed respectively on the patient's distal femur and proximal tibia and prior to rotation to the tibial trial prosthesis;

FIGURE 10 is a schematic view illustrating rotation of the trial tibial prosthesis;

25 FIGURE 10A and 10B are schematic views illustrating alignment of the trial tibial prosthesis and the trial femoral prosthesis;

FIGURE 11 is a schematic view illustrating a preparation of the proximal tibia to receive distal fins of a tibial implant using a fin punch;

30 FIGURE 12 is a perspective view illustrating preparation for bone screws for the tibial tray;

FIGURE 13 is a schematic perspective view illustrating attachment of the plastic insert of the tibia prosthesis to the tibial tray;

5 FIGURE 14 is a partial sectional view of the tibial screw guide portion of the preferred embodiment of the apparatus of the present invention;

FIGURE 15 is an elevational view of the tibial screw drill guide
10 portion of the preferred embodiment of the apparatus of the present invention;

FIGURE 16 is a partial bottom view of the tibial screw drill
guide portion of the preferred embodiment of the apparatus of the
15 present invention;

FIGURE 17 is a partial top view of the tibial screw drill guide
portion of the preferred embodiment of the apparatus of the present
invention;
20

FIGURE 18 is an elevational view of the preferred embodiment
of the fin punch portion of the preferred embodiment of the apparatus
of the present invention;

25 FIGURE 19 is a perspective view illustrating the fin punch
portion of the preferred embodiment of the apparatus of the present
invention;

FIGURE 20 is a fragmentary sectional view illustrating the fin
30 punch of Figures 18-19;

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FIGURE 21 is another fragmentary sectional view illustrating the fin punch of Figures 18-19;

FIGURES 22 is a perspective view of a second embodiment of a tibial trial prosthesis;

FIGURE 23 is an elevational view of a second embodiment of the tibial trial prosthesis;

FIGURE 24 is an exploded perspective view of the trial taper portion of the second embodiment of the tibial trial prosthesis;

FIGURE 25 is a fragmentary sectional view illustrating the trial stem coupler of FIGURES 22-23;

FIGURE 26 is a elevational view of the trial stem coupler of FIGURES 22-23;

FIGURE 27 is a fragmentary sectional view illustrating the trial stem coupler of FIGURES 22-23;

FIGURE 28 is an end view illustrating the trial stem coupler of FIGURES 22-23;

FIGURE 29 is a fragmentary sectional view illustrating another trial stem coupler;

FIGURE 30 is an elevational view of another trial stem coupler;

FIGURE 31 is an elevational view of the trial stem of FIGURES 22-23; and

FIGURE 32 is fragmentary section view of the trial stem of FIGURES 22-23.

5 FIGURES 33-53 are apparatus and prostheses suitable for implanting revisional femoral antibial prosthesis components.

FIGURE 33 is partial perspective view of the preferred embodiment of the apparatus of the present invention;

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FIGURE 34 is a partial frontal view of the preferred embodiment of the apparatus of the present invention;

FIGURE 35 is a partial side view of the preferred embodiment of
15 the apparatus of the present invention;

FIGURE 36 is a perspective exploded view of the preferred embodiment of the apparatus of the present invention;

20 FIGURE 37 is a perspective view of the preferred embodiment of the apparatus of the present invention;

FIGURE 38 is a front view of the preferred embodiment of the apparatus of the present invention;

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FIGURE 39 is a bottom view of the preferred embodiment of the apparatus of the present invention;

FIGURE 40 is a perspective view of the preferred embodiment
30 of the apparatus of the present invention;

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FIGURE 41 is a side, lateral view of the preferred embodiment of the apparatus of the present invention;

FIGURE 42 is a top view of the preferred embodiment of the apparatus of the present invention;

FIGURE 43 is a perspective, exploded view of the preferred embodiment of the apparatus of the present invention;

FIGURE 44 is a schematic view illustrating the cutting of bone tissue from the patient's distal femur using the trial prosthesis body portion of the preferred embodiment of the apparatus of the present invention;

FIGURE 45 is a partial side view of the preferred embodiment of the apparatus of the present invention illustrating one of the wedge insert portions thereof;

FIGURE 46 is a bottom view of the wedge insert portion of the preferred embodiment of the apparatus of the present invention;

FIGURE 47 is a side view of a wedge insert portion of the preferred embodiment of the apparatus of the present invention;

FIGURE 48 is a partial perspective view of a first alternate embodiment of the apparatus of the present invention;

FIGURE 49 is a partial frontal view of the first alternate embodiment of the apparatus of the present invention;

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FIGURE 50 is a partial side view of the first alternate embodiment of the apparatus of the present invention;

FIGURE 51 is a partial perspective view of the second alternate
5 embodiment of the apparatus of the present invention;

FIGURE 52 is a partial frontal view of the second alternate embodiment of the apparatus of the present invention; and

10 FIGURE 53 is a partial side view of the second alternate embodiment of the apparatus of the present invention.

Figures 1-4 and 7 show generally the preferred embodiment of the tibial trial prosthesis of the present invention designated by the
15 numeral 10 in Figure 7. Trial tibial prosthesis 10 is comprised of tray 11, stem or plug 12, and plastic insert 13. The entire trial prosthesis 10 can be rotated after assembly and surgical placement on the patient's distal tibia 9 (see arrow 15 in Figure 10.)

20 Figures 1-2 show trial tray or plate 11. Tray 11 includes an upper surface 16 and a lower surface 17. A shoulder portion 19 extends partially about the periphery 18 at the posterior of tray 11. A central V-shaped slot 20 is provided for allowing a fin punch 43 to be used to make surgical cuts in the proximal tibia corresponding to fins
25 that are a permanent part of the final tibial prosthesis to be implanted. In Figure 11, the surgeon uses mallet 44 to drive fin punch 43.

The fin punch 43 is used after the tibial trial prosthesis 10 has been finally correctly oriented using the method of the present
30 invention. Central opening 42 receives plug 12. Shoulders 37, 39 extend beyond the periphery of opening 42. Plug 12 has proximal 36

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and distal 35 ends. A plurality of openings 21 can be provided in tray 11 for drilling holes that will determine the position of bone screws that hold the final tibial prosthesis to proximal tibia 9. A preferred embodiment of the fin punch will be described more full hereinafter.

5

A pair of spaced apart appendages 22, 23 extend away from the periphery 18 of tray 11. The appendages 22, 23 (see Figures 1-2) have angled openings 24, 25 for receiving bone spikes 26 (See Figure 11). The openings 24, 25 are circular in cross section to conform to the outer surface of bone spikes 26. Each opening 24, 25 forms an acute angle with bottom surface 17 of tray 11. This allows the surgeon to pin the trial prosthesis 10 to the patient's proximal tibia 9 after rotation has been accomplished using the lever 14 to determine the best fit of tray 11 on proximal tibia 9. Bone spikes 26 placed through the angled openings 22, 23 fix the position of the tray 11 with respect to the patient's proximal tibia 9 during punching of the V-shaped opening in the patient's proximal tibia using a fin punch 43 (see Figure 11).

20 In Figures 3-4, plastic trial insert 13 is shown. The insert 13 has a pair of concavities 28, 29 that define articulating surfaces that fit and articulate with condylar portions of a femoral trial prosthesis 45 mounted on the distal end 7 of the patient's femur 6 as shown in Figure 9.

25

A horizontal slot 30 extends from the periphery 18 of insert 13 toward the center thereof. Slot 30 is generally parallel to the generally flat underside 13A of insert 13, generally parallel thereto slot 13 is positioned in between underside 13 and articulating surfaces 28, 29 as shown.

30

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As shown in Figure 4, the slot 30 terminates before reaching the anterior side 31 of insert 13. A pair of annular shoulders 32, 33 retain the lever tab 34 at one end of line 14, and more particularly the tab end 34 thereof so that rotation of the lever 14 also rotates the insert 13, the tray 11, and the plug or stem 12 to which tray 11 is affixed. In Figure 10, the entire assembly of tray 11, insert 13, and stem 12 are seen being rotated as illustrated by the curved arrow 15. Tab 34 can be used to engage and manipulate insert 13. Thus, lever 14 and its tab 34 can be used to aid in removal of insert 13 from tray 11, or in attaching insert 13 to tray 11.

In Figure 6, 6A and 6B, the trial stem 12 provides a distal end 35 that is shaped to conform to the transverse cross section of opening 42 (see Figure 6A) and proximal end 36. The proximal end 36 has a pair of spaced apart shoulders 37, 39 that extend away from the central longitudinal axis of the stem. Shoulders 37, 39 define a means of engaging the stem 12 at top surface of the tray 11 upon assembly when the surgeon is building a trial prosthesis.

The shoulders 37, 39 extend beyond the outer surface 41 of stem 12 and thus beyond the central opening 42 in tray 11. The slot 38 between shoulders 37, 39 allows the fin punch to fit between the shoulder 37, 38. Slot 38 is positioned between the laterally extending shoulders 37, 39. The slot 38 extends only about halfway along the length of the trial stem, terminating at surface 40.

In Figure 8, the trial femoral prosthesis 45 is shown affixed to the patient's distal femur 7. The distal femur is surgically prepared with anterior and posterior flat cuts that are parallel, a distal cut that is perpendicular to the anterior and posterior cuts, and chamfer cuts (anterior and posterior) that extend diagonally respectively between

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the distal cut and the anterior and posterior cuts. Such a surgical preparation of the distal femur 7 to receive a femoral prosthesis, or trial femoral prosthesis is known in the art.

5 The trial femoral prosthesis 45 of the present invention has a pair of curved articulating condylar surfaces 46, 47. The rear surface 48 of trial femoral prosthesis 45 is sized and shaped to fit the surgically prepared distal femur 7. Trial femoral prosthesis 45 has a pair of flat cutting guide surfaces 49, 50 that allow the surgeon to form
10 surgical cuts 52, 53 forming a V-shaped recess in the patient's distal femur 7. Blade 54 in Figure 8 is seen resecting the distal femur 7 with cuts 52, 53 to form recess 51. The formed recess 51 allows placement of a final femoral prosthesis.

15 In Figures 9-10, trial tibial prosthesis 10 has been installed by the surgeon on the patient's proximal tibial 9. The surgeon has also installed a trial femoral prosthesis 45 on the distal femur 7.

20 Using the method and apparatus of the present invention, the surgeon can determine the best fit for the tibial trial prosthesis 10 in relation to the trial femoral prosthesis 45. Trial femoral prosthesis 45 (Figure 8) can be drilled at openings 55, 56 and affixed to the distal femur 7 using bone screws or pegs. These openings 55, 56 can also define the position of pegs that attach the final femoral prosthesis to
25 the distal femur 6.

30 In Figure 10 and 10A-10B, the trial prosthesis 10 is shown mounted on the patient's proximal tibia 9. Lever 14 fits slot 30 of the trial prosthesis insert 13. Using the lever 14, the surgeon can now rotate the trial prosthesis 10 about its stem portion 12, as shown by

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the curved arrows 15 in Figure 10. This can be done as the surgeon rotates the knee through its full range of motion to obtain the best fit.

The surgeon rotates the lever 14 to place the trial prosthesis 10 in a desired position (see Figure 10, 10A and 10B). The surgeon can also rotate the tibia relative to the femur (see arrow 27 in Figure 9) through a full range of motion. If the surgeon is not satisfied with the fit, the lever 14 can be used to reposition the trial prosthesis 10, and rotate the knee again through a full range of motion. The lever 14 and its tab 34 can also be used to change inserts 11, such as a different size or different thickness insert 11. The procedure can be repeated until the surgeon is completely satisfied with the orientation of trial prosthesis 10 in relation to trial femoral prosthesis 45.

In Figures 10A and 10B, alignment lines are provided on the tibial trial prosthesis 10 and on the femoral trial prosthesis 45. The femoral trial prosthesis 45 provides a straight alignment line 45A that tracks a path coplanar with the arc of rotation of the knee during its normal flexion. Similarly, an alignment line 13A is provided on the anterior portion of insert 13. The alignment mark 13A is placed at the periphery 18 of insert 13. Alignment line 13A is a straight line that falls in a plane defined by the arc of rotation of the knee during flexion. When the knee is at full extension as shown in Figure 10A, the alignment marks 45A and 13A can be aligned by simply rotating the tibial trial prosthesis 10 about its stem as shown in Figures 10A and 10B using the lever 14.

Since the surgeon will first attach a trial femoral prosthesis 45, the lever 14 allows the surgeon to then place and rotate the trial tibial prosthesis 10 until the alignment marks 45A and 13A are aligned as shown in Figure 10A. In this manner, the surgeon knows that the trial

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tibial insert 10 is properly aligned with the trial femoral prosthesis 45 that he or she has attached to the patient's distal femur 7. The alignment marks 45A, 13A would desirably be affixed during manufacture. When aligned as shown in Figure 10A, the marks 13A, 45A insure optimum contact between the femoral articulating surfaces 46, 47 and the corresponding tibial articulating surfaces 28, 29 on the insert 13.

Additional alignment marks 18A, 18B are provided on the periphery of the trial tibial prosthesis tray 11. The marks 18A, 18B are linear marks that are generally perpendicular to the flat surfaces 16, 17 of the trial prosthesis tray 11. The alignment marks 18A, 18B guide the surgeon to inscribe marks 9A, 9B during surgery on the patient's proximal tibia 9 after trial femoral prosthesis 45 has been installed on the distal femur 7, and after the alignment line 13A has been aligned with the alignment line 45A as shown in Figure 10. This is desirable because the lines 9A, 9B function as reference lines that will enable the surgeon to properly align the final tibial prosthesis on the patient's proximal tibia 9.

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In Figures 12 and 14-17, there can be seen screw drill guide 57. The drill guide 57 can be used to install a final tibial prosthesis 64 on the patient's proximal tibia 9 once the surgeon has decided upon a particular size and shape of tibial implant 64 based upon the use as
aforedescribed of the tibial trial prosthesis 10. Drill guide 57 includes a handle 58 for holding and manipulating the drill guide 57.

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A guide sleeve 59 is generally cylindrically shaped, and provides a plurality of bores through bone screws can be placed for
attaching the final tibial prosthesis 64 to the patient's proximal tibia 9. Guide sleeve 59 preferably includes four (4) screw guide bores. A

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straight bore 60 tracks the central longitudinal axis of guide sleeve 59. A plurality of angled bores 61-63 extend from the upper surface to the lower surface of the guide sleeve 59, all of the bores 61-63 exiting at common opening 65.

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In Figure 12, there can be seen a drill 66 being guided by the surgeon through one of the bores 60-63 of the guide sleeve 59. The drill 66 is simply placed in the desired bore 60-63 and driven into one of the openings 68 of the tibial prosthesis 64 using drill driver 67. The surgeon inserts a bone screw through the prepared hole then places the final plastic insert 69 on the prosthesis 64 and hammers it into place using mallet 44, hammering in the direction of arrow 70.

Figures 18-21 illustrate the all poly plastic fin punch of the present invention designated generally by the numeral 71. In Figures 1-2, fin punch 71 has a cylindrical section 72 with a pair of blades 73, 74 joined at vertical plate 93 and extending downwardly with respect to the central axis of the cylindrical section 72. A horizontal frame section 76 forms a connection between the cylindrical sections 72 and the pair of blades 73, 74. A generally U-shaped slot 75 is positioned between the blade member 73, 74.

The horizontal section 76 has a generally flat upper surface 77. Each of the blades 73, 74 provides a respective inclined cutting edge 78, 79. The cutting edge 78 begins at pointed distal end 80 and extends to horizontal surface 84 of section 76. The inclined cutting edge 79 begins at pointed distal end 81 of blade 74 and extend to horizontal surface 84 of section 76. A plurality of notches or stepped portions 85-90 can be seen along each of the inclined cutting surfaces 78, 79 of the blades 73, 74.

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Each of the stepped portions 85, 90 includes a vertical surface 91 and a horizontal surface 92. The step portions combined with the size of slot 20 of trial tray 11 to limit the depth of cut that is made by the fin punch 71. The punch 71 only goes down to that particular stepped portion or notch 85-90 that can be fitted through the slot 20 depending upon the width of the slot 20. For example, the punch 71 only goes down to the fourth notch for a size "4" tibial prep-plate 11 because the slots 20 in the trial plate 11 for a size "4" or a given distance wide. They would be provided as wider slots 20 for example on sizes "5" and "6". The slot 20 would be smaller for an over all width for a size "3" or smaller. This sizing concept also corresponds to the implant design since the fins or blades 73, 74 get larger in width the larger the size.

Figures 22-32 illustrate tibial trial prosthesis 94 that can be used with a tibial prep plate tray 95. For purposes of the embodiment of Figures 22-32, prep plate tray 95 can be assumed to have the same configuration and structure as tray 11 described in Figures 1 and 2.

Figures 22-23 show generally the second embodiment of the tibial trial prosthesis designated generally by the numeral 94. Tibial trial prosthesis 94 includes a prep plate or tray 95 that is attached to trial taper 96, trial stem coupler 97 or 97A, and trial stem 98.

The trial taper 96 is shown generally in Figure 24. Trial taper 96 includes a generally cylindrical bushing 99 having an enlarged integral head portion 100. An assembly bolt 101 can be placed through counterbore 104 of bushing 99. The counterbore 104 is shaped to retain the head 103 of bolt 101, allowing only the threaded section 102 to pass therethrough as shown in Figure 24. Bushing 99

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and its enlarged head 100 are coupled to stem 113 that has a frustroconical surface 113A thereon at the lower distal 105 end portion.

5 The proximal 106 end of stem 113 provides a counterbore 107 that is sized and shaped to receive bushing 99 and the threaded portion 102 of bolt 101. Further, the counterbore 107 includes an internally threaded section for engaging the threads 102 of bolt 101 upon assembly. The bolt head 103 can have a hexagonal recess, for
10 example, for accepting an allen wrench that impart torque to the bolt 101 during assembly to stem 113.

 As with the trial tray 11 of Figures 1-2, a central opening 42 can be provided into plate 95. The opening 92 is sized and shaped to
15 receive a reduced section 110 of stem 113 at proximal end 106 thereof. A thickened 108 section of stem 113 extends between annular shoulder 109 and frustroconical surface 113A. The thickened section 108 can carry a pair of longitudinally extending slots 111, 112 that receive the blades of fin punch 71. Thus, the trial plate can have
20 a V-shaped slot as with the slot 20 on plate 11 of Figures 1-2. After the bushing 99, bolt 101 and stem 113 have been assembled, the slot 20 extends away from stem 113 and the blades of fin punch 71 can pass on opposites sides of the trial taper 96.

25 A flat surface 114 on stem 113 cooperates with a similar flat surface of trial stem coupler 97, 98. In Figures 25, 28, a first trial stem coupler 97 is shown. In Figures 29-32, a second trial stem coupler 97A is shown that includes an angled bore.

30 In Figures 25-28, trial stem coupler 99 includes an externally threaded smaller diameter section 115 and a larger diameter

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cylindrical section 116 that is unthreaded. The section 116 provides a frustroconical bore 118 surrounded by a thick annular side wall 117 and a thin annular side wall 122. An annular shoulder 120 extends between the thick annular side wall 117 and the thin annular side wall 122. A transverse bore 119 extends at generally right angles to the frustroconical bore 118 as shown in Figure 25. Flat surface 121 is positioned at thin annular side wall 122. The flat surface 121 mates with the flat surface 114 on stem 113 upon assembly of trial taper 96 and coupler 97.

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In Figures 29-32, coupler 97A is shown having an internal inclined frustroconical bore 126. The coupler 97A includes an externally threaded smaller diameter section 123, a larger diameter unthreaded cylindrical section 124 surrounded by a thick annular wall 125 and a thin annular wall 130. As with the coupler 97, the coupler 97A includes a transverse bore 127. An annular shoulder 128 extends between the thick annular wall 125 and the thin annular wall 130. A flat surface 129 at thin annular surface 130 cooperates with a corresponding flat surface 114 on stem 113 upon assembly of trial taper 96 and the trial stem coupler 97A.

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In Figure 29, axis 131 represents a normal axis that is the central longitudinal axis of threaded cylindrical section 123. The axis 132 is an offset axis that is the central longitudinal axis of inclined frustroconical bore 126. The angle between the normal axis 131 and the inclined axis 132 can be, for example, between about 3 and 8 degrees.

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In Figures 31-32, the trial stem 98. Trial stem 98 includes a lower frustroconically-shaped distal end 133, a generally cylindrically-shaped elongated section 134, and a thickened proximal end portion

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135. The proximal end portion provides an internally threaded bore
136 that can form a connection with either the externally threaded
section 115 of trial stem coupler 97 or the externally threaded section
123 of trial coupler 97A. Upon assembly, the flat annular surface 137
5 of proximal end portion 135 mates with the flat annular surface 138 of
trial coupler 97 or the flat annular surface 139 of trial coupler 97A.

In Figures 33-43, there can be seen the preferred embodiment
of the apparatus of the present invention, designated by the numeral
10 210 in Figures 36-37 and 40-43. Trial femoral prosthesis 210
includes femoral prosthesis body 211 that is affixed to the patient's
distal femur during knee replacement surgery. Body 211 includes an
anterior portion 212, a pair of posterior condylar portions 213, 214 and
a pair of distal condylar portions 215, 216.

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The anterior portion 212 has an anterior articulating surface 217.
The posterior condylar portions have posterior condylar articulating
surfaces 218, 219. The distal condylar surfaces 215, 216 have
respective distal condylar articulating surfaces 220, 221. A vertical
20 line 222 extends from anterior articulating surface 217 towards distal
condylar articulating surfaces 220, 221. The line 222 is a reference
line that is used in combination with a similar reference mark on a
tibial trial prosthesis. The surgeon rotates the tibial trial prosthesis
tray until a corresponding mark on the tibial trial prosthesis tray lines
25 up with the line 222 on the femoral trial prosthesis. These alignment
lines such as 222 are preferably positioned during manufacture to
maximize articulating contact between a femoral trial prosthesis 210
and a trial femoral prosthesis. Once the desired locations for the trial
components are determined, the final implant components are placed
30 in the same positions.

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As shown in Figures 35 and 44, the prosthesis body 211 provides a number of non-articulating surfaces 223-227. These non-articulating surfaces 223-227 include an anterior flat non-articulating surface 223, a flat distal non-articulating surface 225, a flat posterior non-articulating surface 227, and a pair of chamfer non-articulating surface 224, 226. The surface 226 is an anterior non-articulating chamfer surface. The surface 225 is a non-articulating posterior chamfer surface.

10 A stem 228 extends from surface 225 upwardly along a vertical line that is generally parallel to the plane of surfaces 227 and 223. Stem 228 can be provided in different angles of valgus. An angulated thickened section 229 extends from stem 228 to non-articulating surface 223, functioning as a reinforcement to anterior portion 212 in
15 the vicinity of several guide slots 230-235.

The cutting blade guide slots act as cutting guides 230-235 act as cutting guides for a saw blade 236 (or osteotome) used in cutting the patient's distal femur (See Figure 44) to receive a trial wedge
20 insert designated by the numeral 240 in Figure 36. Insert 240 can be secured to the medial or the lateral side of non-articulating surface 225 using a bolt or screw 237 such as the countersunk screw 237 shown in Figure 36. Openings 238, 239 are internally threaded openings that threadably connect with the threads 241 of screw 237
25 for example.

The plurality of cutting guide slots 230-235 include a plurality of medial slots and a plurality of lateral slots. The slots 230-231 are diagonally extending slots that are coplanar with the surface 224 as
30 shown in Figure 35. The slots 232 and 234 are parallel to one another and to surface 225 as shown in Figures 35 and 36. Surfaces

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233, 235 are parallel to surfaces 225. In Figure 34, the medial cutting surfaces are designated as 231, 233 and 235. The lateral cutting guide slots are designated as 230, 232, and 234.

5 In Figures 43 and 45-47, there can be seen more particularly the construction of a first wedge insert 240. The wedge insert 240 has an anterior section 250 and a posterior section 248. The anterior section 250 includes an upper surface 242 and a lower surface 243. The upper and lower surfaces 242, 243 are generally planar and parallel
10 to one another. However, the lower surface 243 can have a peripheral raised portion 247 that can be used to engage a similarly shaped troth provided on surface 225 of trial prosthesis body 211.

The lower surface 243 of anterior section 250 has a pin 245 that
15 is cylindrically shaped as seen in Figure 45. The pin 245 engages a similarly shaped opening 254 in body 211 at surface 225, as shown in Figure 43.

Insert 240 also includes a posterior section 248 that carries a
20 cutting edge 249 that is used in shaping the patient's distal femur F during placement of the trial prosthesis when wedges are to be used. Posterior section 248 has a plurality of flat surfaces 251-253, as shown in Figure 43. Additionally, the posterior section 248 provides flat side surfaces 255, 256. The anterior section 250 has an inclined
25 surface 261, that is generally parallel to the anterior chamfer surface 224 of the trial prosthesis 211 upon assembly, as shown in Figures 40-43. Similarly, the surface 252 of wedge insert 240 is generally parallel to the posterior chamfer surface 226 of the trial prosthesis body 211 upon assembly.

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As with the cutting edge 249 of the wedge 240, the trial prosthesis body 211 can provide posterior condylar cutting edges 257, 258 associated with the condylar portions 213, 214, as shown in Figures 36 and 44 and/or an anterior cutting edge 261 associated with anterior portion 212 as shown in Figures 34-35. These cutting edges 257, 258, and 261 help trim bone from the patient's distal femur in a revision case when the surgeon is applying the trial prosthesis body 211 to the distal femur after a previously implanted prosthesis has been removed.

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In Figure 44, the surgeon's saw blade 236 is shown tracking one of the selected guide slots 230-235. This allows the surgeon to trim bone along a desired line such as the line of cut indicated schematically as 259 in Figure 43.

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In Figure 47, the wedge insert 260 is thicker than the insert of Figure 45. If the surgeon desires to remove bone from a distal femur F by following the reference line 259 shown in Figure 44, the surgeon would select either the cutting guide slot 234 or 235 (see Figure 34).

20 In such a case, less bone is being removed and therefore the surgeon would select a wedge insert 240. However, if the surgeon were to remove more bone, the surgeon would select the cutting guide slot 232 or 233 as shown in Figures 34 and 44. In this case, the surgeon would select the thicker wedge insert 260. It should be understood
25 that other than thickness, the inserts 240 and 260 are the same.

Figures 48 - 50 show an alternate embodiment of the apparatus of the present invention. The embodiment of Figures 48 - 50 provides the same trial prosthesis body 211 having an anterior portion 212,
30 condylar portions 213, 214 and distal articulating portions 215, 216. The body 211 shown in Figures 48 - 50 can be used with inserts 240,

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260 as with the embodiment of Figures 33 - 47. In the embodiment of Figures 48 - 50, an enlarged track 262, 263 is provided respectively for each condylar portion 213, 214. The tracks 262, 263 are generally rectangular in a cross section as shown in Figure 50. This rectangular cross section allows an osteotome such as 264, 265 to be used to shave bone tissue from the patient's distal femur in a chamfer cut fashion. The non-articulating surface 226 of the prosthesis body 211 forms a portion of the tracks 262, 263. An elongated C-shaped slot 266 forms one side portion of each track. A similar C-shaped slot 267 forms an opposing side portion of the tracks 262, 263. During use, the surgeon can use either osteotome 264 or 265 with either track 262 or 263 respectively to shave bone tissue from the patient's distal femur.

15 In the embodiment of Figures 51 - 53, designated generally by the numeral 268, a trial prosthesis body 211 is shown having the same overall construction as that of the preferred embodiment, providing an anterior portion 212, a pair of condylar portions 213, 214, a distal articulating portion 215, 216, and a plurality of flat intersecting non-articulating surfaces 223, 227. In the embodiment of Figures 51 - 53, the trial prosthesis 268 includes medial and lateral posterior chamfer cutting slots 269, 270. In the embodiment of Figures 51 - 53, the surgeon can use either of the posterior chamfer cutting slots 269, 270 to track a saw blade during a trimming of the patient's distal femur at the non-articulating surface 226. As with the slots 230 - 235, the posterior chamfer cutting slots 269, 270 are spaced apart. Each posterior chamfer slot 269, 270 extends between an articulating surface 215, 216 (and the non-articulating surfaces 225, 226),

30 The following table lists the parts numbers and parts descriptions as used herein and in the drawings attached hereto.

PARTS LIST

	<u>Part Number</u>	<u>Description</u>
5	6	femur
	7	distal femur
	8	tibia
	9	proximal tibia
	9A	tibial alignment mark
10	9B	tibial alignment mark
	10	trial prosthesis
	11	tray
	12	stem
	13	insert
15	13A	underside
	14	handle
	15	arrow
	16	upper surface
	17	lower surface
20	18	periphery
	18A	insert alignment mark
	18B	insert alignment mark
	19	raised shoulder portion
	20	V-shaped slot
25	21	opening
	22	appendage
	23	appendage
	24	angled opening
	25	angled opening
30	26	bone spike
	27	arrow

		59	
	28		concavity
	29		concavity
	30		slot
	31		anterior side
5	32		shoulder
	33		shoulder
	34		tab
	35		distal end
	36		proximal end
10	37		shoulder
	38		slot
	39		shoulder
	40		surface
	41		surface
15	42		opening
	43		fin punch
	44		mallet
	45		trial femoral prosthesis
	45A		alignment line
20	46		condylar articulating surface
	47		condylar articulating surface
	48		rear surface
	49		cutting guide surface
	50		cutting guide surface
25	51		V-shaped recess
	52		surgical cut
	53		surgical cut
	54		blade
	55		opening
30	56		opening
	57		screw drill guide

		60	handle
		58	guide sleeve
		60	straight bore
		61	angled bore
5		62	angled bore
		63	angled bore
		64	tibial prosthesis
		65	common opening
		66	drill
10		67	driver
		68	opening
		69	plastic insert
		70	arrow
		71	fin punch
15		72	cylindrical section
		73	blade
		74	blade
		75	slot
		76	horizontal section
20		77	flat surface
		78	inclined cutting edge
		79	inclined cutting edge
		80	pointed distal end
		81	pointed distal end
25		82	proximal end
		83	internally threaded bore
		84	horizontal surface
		85	stepped portions
		86	stepped portions
30		87	stepped portions
		88	stepped portions

		61	
	89		stepped portions
	90		stepped portions
	91		vertical surface
	92		horizontal surface
5	93		vertical plate
	94		tibial trial prosthesis
	95		prep plate tray
	96		trial taper
	97		trial stem coupler
10	97A		trial stem coupler
	98		trial stem
	99		bushing
	100		head
	101		bolt
15	102		threads
	103		head
	104		counterbore
	105		distal end
	106		proximal end
20	107		counterbore
	108		thickened section
	109		annular shoulder
	110		reduced section
	111		longitudinal slot
25	112		longitudinal slot
	113		stem
	113A		frustroconical surface
	114		flat surface
	115		externally threaded section
30	116		cylindrical section
	117		thick annular side wall

		62	
	118		frustroconical bore
	119		transverse bore
	120		annular shoulder
	121		flat surface
5	122		thin annular side wall
	123		externally threaded section
	124		cylindrical section
	125		thick annular wall
	126		inclined frustroconical bore
10	127		transverse bore
	128		annular shoulder
	129		flat surface
	130		thin annular wall
	131		normal axis
15	132		inclined axis
	133		distal end
	134		cylindrically-shaped section
	135		proximal end
	136		internally threaded bore
20	137		flat annular surface
	138		flat annular surface
	139		flat annular surface
	F		femur
	210		trial prosthesis assembly
25	211		prosthesis body
	212		anterior portion
	213		condylar portion
	214		condylar portion
	215		distal condylar portion
30	216		distal condylar portion
	217		anterior articulating surface

		63	
	218		articulating surface
	219		articulating surface
	220		articulating surface
	221		articulating surface
5	222		reference line
	223		non-articulating surface (anterior)
	224		non-articulating surface (anterior chamfer)
10	225		non-articulating surface (distal)
	226		non-articulating surface (posterior chamfer)
15	227		non-articulating surface (posterior)
	228		stem
	229		thickened section (canopy)
20	230		guide slot (lateral chamfer slot)
	231		guide slot (medial chamfer slot)
25	232		guide slot (large wedge slot- lateral)
	233		guide slot (large wedge slot- medial)
	234		guide slot (small wedge slot- lateral)
30	235		guide slot (small wedge slot- medial)

		64	
	236		saw blade
	237		assembly screw
	238		opening
	239		opening
5	240		wedge insert (small)
	241		threads
	242		upper surface (of wedge)
	243		lower surface (of wedge)
	244		peripheral edge
10	245		pin
	246		clip
	247		raised portion (of lower surface)
	248		posterior section
15	249		cutting edge (of wedge)
	250		anterior section
	251		surface (which creates cutting edge)
	252		flat surface
20	253		flat surface
	254		opening
	255		side surface
	256		side surface
	257		cutting edge (of femoral trial)
25	258		cutting edge (of femoral trial)
	259		reference line
	260		wedge insert (large)
	261		cutting edge
	262		osteotome track
30	263		osteotome track
	264		osteotome

		65	
	265		osteotome
	266		slot
	267		slot
	268		trial prosthesis
5	269		posterior chamfer cutting slot
	270		posterior chamfer cutting slot

10 Because many varying and different embodiments may be
made within the scope of the inventive concept herein taught, and
because many modifications may be made in the embodiments
herein detailed in accordance with the descriptive requirement of the
law, it is to be understood that the details herein are to be interpreted
15 as illustrative and not in a limiting sense.

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CLAIMS

1. A trial knee prosthesis comprising at least
 - (a) a femoral trial prosthesis
 - 5 (b) a tibial trial prosthesis having a periphery with an open ended socket at the periphery.
 - (c) a handle for manipulating the femoral trial prosthesis and tibial trial prosthesis relative to one another.
- 10 2. A trial knee prosthesis as claimed in claim 1 comprising:
 - a) a femoral trial prosthesis;
 - b) a tibial trial prosthesis having a periphery with an open ended socket at the periphery;
 - c) a handle for manipulating the femoral trial prosthesis and
 - 15 tibial trial prosthesis relative to one another; and
 - d) said handle being slideably attachable to the tibial trial prostheses at the socket, said handle comprising in part a tab member that closely fits within the socket of the tibial trial prosthesis, and wherein the tab member and socket are correspondingly sized and
 - 20 shaped .
3. A trial knee prosthesis as claimed in claim 1 for articulating with a patient's femoral condylar articulating surface comprising;
 - a) a tibial trial prosthesis that includes a metallic trial tibial tray
 - 25 with a stem that fits the patient's intramedullary canal and a plastic articular insert that is connectable to the tray, the insert having an articulating surface for receiving and articulating with a patient's correspondingly shaped femoral condylar articulating surface;
 - b) a handle for manipulating the trial tibial prosthesis, said
 - 30 handle having means for forming a detachable connection with the tibial trial prosthesis;

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- c) said tibial trial prosthesis and said handle being rotationally movable together, independently of said femoral articulating surface, for enabling a surgeon to use the handle to selectively position the trial tibial prosthesis in a desired rotational position relative to the femoral condylar articulating surface.

4. A trial knee prosthesis as claimed in claim 1 for attachment to a patient's long bone during knee joint replacement surgery comprising:
- a) a trial prep member having means for attaching the prep member to a long bone adjacent the patient's knee joint, the prep member providing a trial articulating surface;
- b) an elongated trial stem that fits the patient's long bone intramedullary canal;
- c) a trial stem taper that is removably attachable to the prep plate member; and
- d) a trial stem coupler that forms a connection between the trial stem taper and the trial stem, said coupler comprising a smaller diameter section adapted to form a connection with the trial stem and a larger diameter section adapted to form a connection with the trial stem taper, said larger diameter section providing a shaped connecting surface that forms a connection with a correspondingly-shaped connecting surface of the trial stem taper.

5. A trial knee prosthesis as claimed in claim 1 wherein the tibial trial prosthesis comprises:
- a) a prep plate tray;
- b) an elongated trial stem;
- c) a trial stem taper that is attachable to the prep plate tray; and
- d) a trial stem coupler that forms a connection between the trial stem taper and the trial stem, said coupler comprising a smaller diameter section adapted to form a connection with the trial stem and

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a larger diameter section adapted to form a connection with the trial stem taper, said larger diameter section providing a shaped connecting surface that forms a connection with a correspondingly-shaped surface of the trial stem taper.

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6. A trial knee prosthesis as claimed in claim 1, wherein the trial femoral prosthesis comprises:

a) a trial prosthesis body having a distal articulating surface and a proximal non-articulating surface, said articulating surface including
10 medial and lateral condylar portions;

b) a stem member that extends from the non-articulating surface;

c) a trial insert that is connectable to the trial prosthesis body at the non-articulating surface on either the medial or lateral side of the
15 trial prosthesis;

d) a cutting surface for cutting the patient's distal femur during a placement of the trial prosthesis body on the patient's distal femur.

7. A trial knee prosthesis as claimed in claim 1, wherein the trial
20 femoral prosthesis comprises:

a) a trial prosthesis body having a distal articulating surface and a proximal non-articulating surface, said articulating surface including medial and lateral condylar portions, said distal non-articulating surface including a plurality of flat intersecting surfaces that include
25 distal, anterior chamfer and posterior chamfer surface;

b) a wedge trial insert that is connectable to the trial prosthesis body at the proximal non-articulating surface and extending toward the anterior and posterior chamfer surfaces;

c) a plurality of cutting guide slots that extend through the trial
30 body, each slot communicating with the articulating surface and the non-articulating surface.

8. A trial knee prosthesis as claimed in claim 1 wherein the trial femoral prosthesis comprises:

- 5 a) a trial prosthesis body having a distal articulating surface and a proximal non-articulating surface, said articulating surface including medial and lateral condylar portions, said proximal non-articulating surface including a plurality of flat intersecting surfaces that include distal, anterior chamfer and posterior chamfer surfaces;
- 10 b) a trial insert that is connectable to the trial prosthesis body at the proximal non-articulating surface and extending along a path spanning between the anterior and posterior chamfer surfaces;
- c) a plurality of cutting guide slots that extend through the trial body along a line that extends along an anterior to posterior line, each slot communicating with the articulating surface and the non-
- 15 articulating surface; and
- d) each of said cutting guide slots comprised of parallel flat surface that each define a plane.

9. A tibial cutting instrument for preparing a patient's proximal tibia to receive a trial knee prosthesis as claimed in claim 1 comprises:

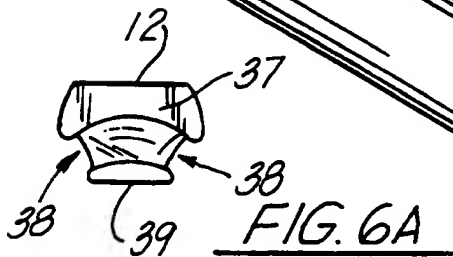
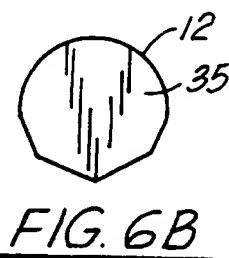
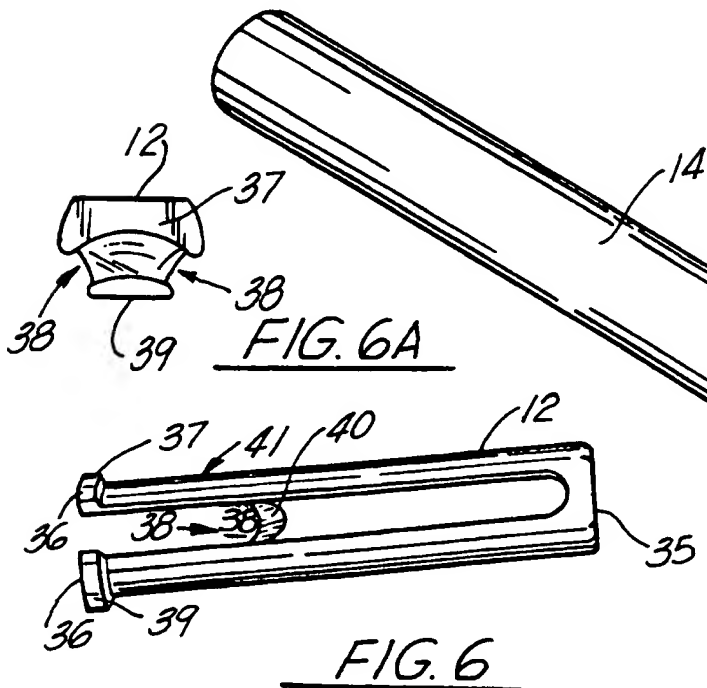
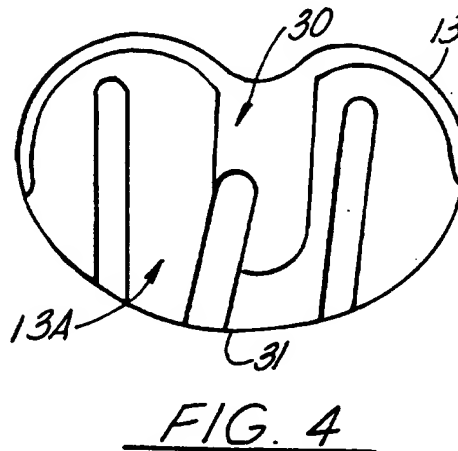
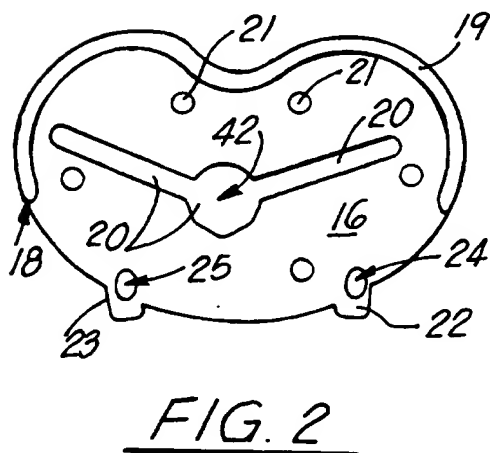
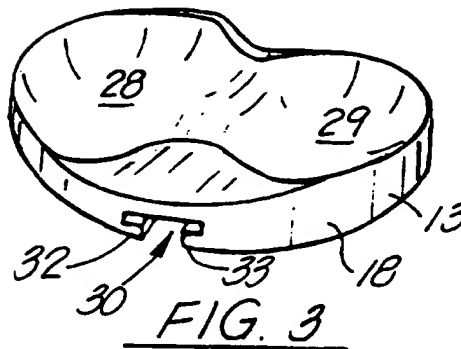
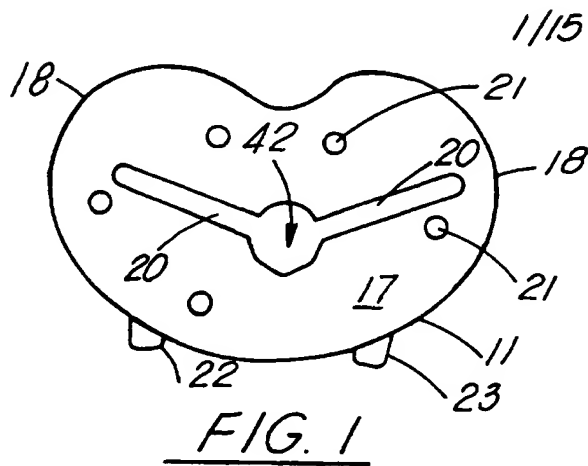
- a) cutting block means for preparing the proximal tibia with a transverse surgical cut;
- 25 b) trial prosthesis means that can be surgically implanted to the proximal tibia, said prosthesis including plurality of trays of different sizes, a plurality of stems of different sizes that are each connectable to a plurality of the trays and a plurality of plastic liners that fit the trays; and
- 30 c) means, forming a connection with the plastic liner, for rotating the prosthesis means after implantation.

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10. A method of implanting a femoral and tibial knee prosthesis, using a trial knee prosthesis as claimed in claim 1 comprising the steps of:

- 5 a) forming a plurality of surgical cuts on the patient's distal femur;
- b) fitting a femoral trial prosthesis to the surgically prepared distal femur, the femoral trial prosthesis having a femoral articulating surface and a non-articulating surface that fits the patient's distal femur at the surgical cuts;
- 10 c) forming a transverse cut on the patient's proximal tibia;
- d) placing a tibial trial prosthesis on the patient's proximal tibia, said tibial trial prosthesis including a tibial stem that fits the patient's intramedullary canal, a metallic tibial tray, and a plastic trial insert that fits the tibial tray said plastic insert having a tibial articulating surface
- 15 that articulates with the femoral articulating surface;
- e) placing the femoral articulating surface against the tibial articulating surface during the surgical;
- f) moving the patient's tibia through a range of motion during which the femoral and tibial articulating surfaces articulate with each
- 20 other;
- g) rotating the tibial trial prosthesis about its stem with an instrument that engages the plastic insert so that the instrument can be used to remove the plastic insert for replacement with another insert of a different size;
- 25 h) wherein articulation of the femoral trial prosthesis and tibial trial prosthesis in step "g" can be observed by the surgeon during the surgical procedure when:
- 1) the patient's tibia is moved through a range of motion relative to the patient's femur; and
- 30 2) the trial tibial prosthesis is moved into different rotational trial positions.

11. A method of implanting a knee implant that includes corresponding femoral and tibial knee prosthesis components using a trial knee prosthesis as claimed in claim 1 comprising the steps of:
- 5 a) forming a plurality of surgical cuts on the patient's distal femur;
- b) fitting a femoral trial prosthesis to the surgically prepared distal femur, the trial prosthesis having a femoral articulating surface;
- c) forming a transverse cut on the patient's proximal tibia;
- 10 d) building a tibial trial prosthesis for placement on the patient's proximal tibia, said tibial trial prosthesis being constructed from a plurality of trays, stems and inserts including a selected tibial stem that fits the patient's intramedullary canal, a selected metallic tibial tray, and a selected plastic trial insert having a tibial articulating
- 15 surface;
- e) placing the trial tibial prosthesis on the patient's proximal tibia;
- f) placing the femoral articulating surface against the tibial articulating surface;
- 20 g) attaching a lever to the plastic insert;
- h) moving the patient's tibia through a range of motion during which the trial femoral and trial tibial articulating surfaces articulate with each other;
- i) rotating the tibial trial prosthesis about its stem so that
- 25 articulation of the femoral trial prosthesis and tibial trial prosthesis can be obtained by the surgeon during the surgical procedure when:
- 1) the patient's tibia is moved through a range of motion; and
- 2) the trial tibial prosthesis is moved into different rotational trial positions.



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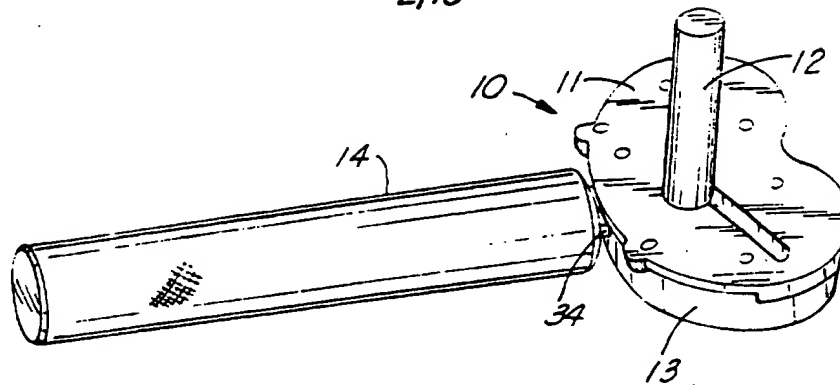


FIG. 7

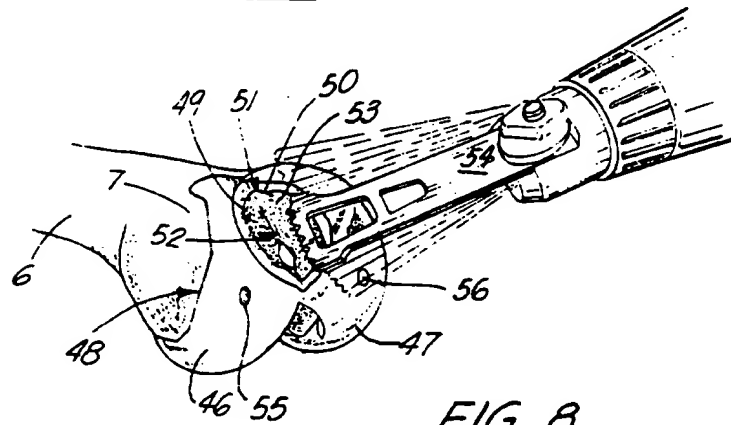


FIG. 8

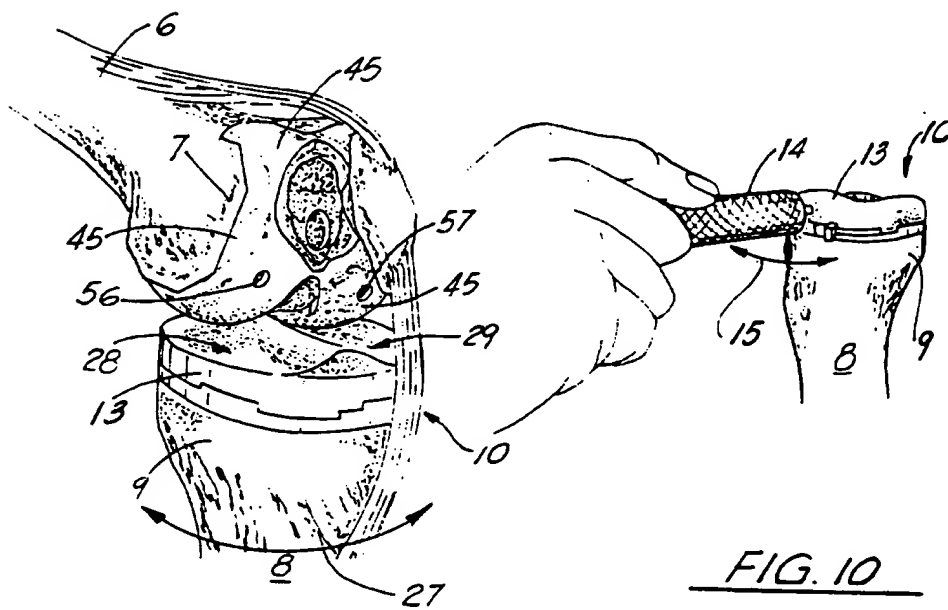
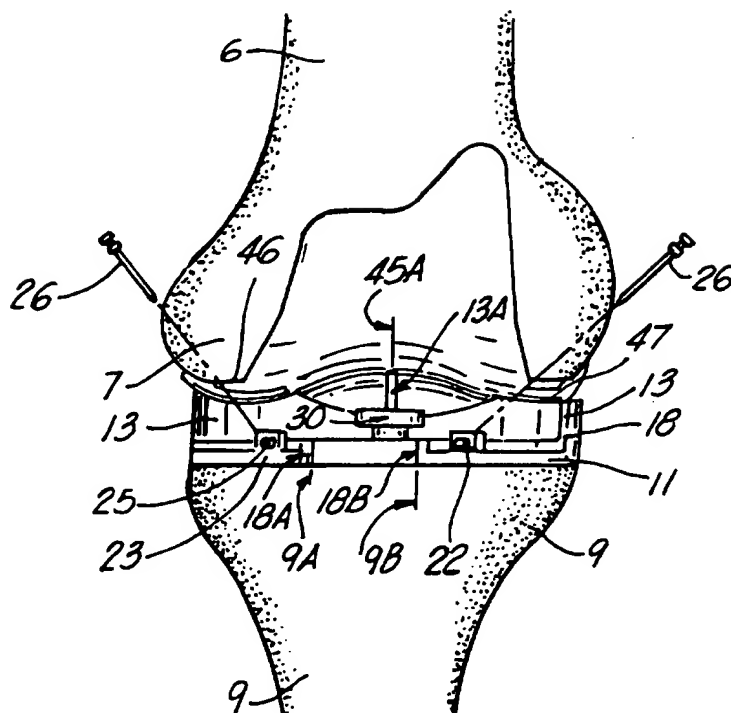
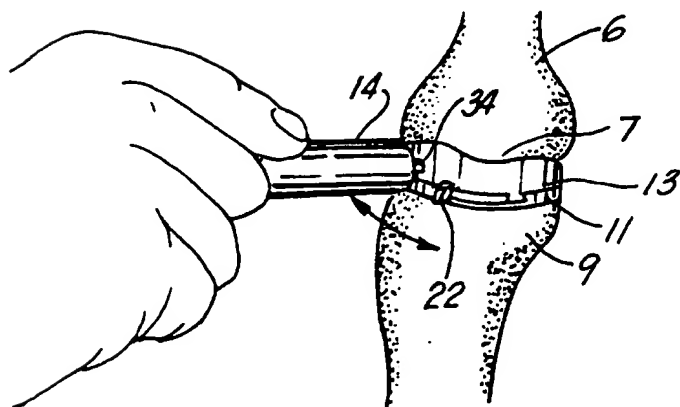


FIG. 9

FIG. 10

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FIG. 10AFIG. 10B

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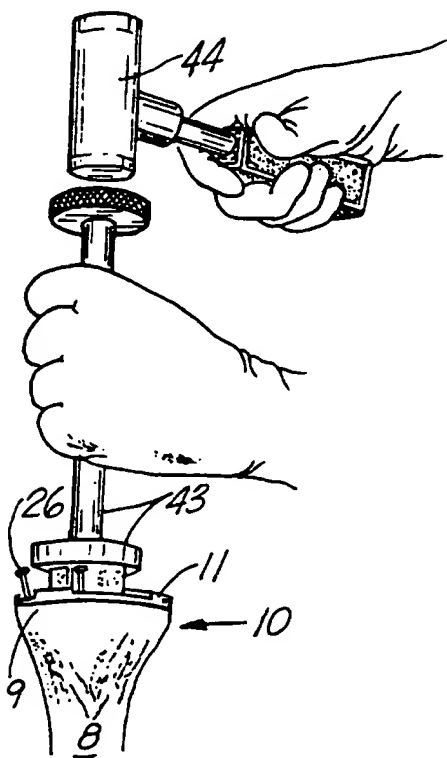


FIG. 11

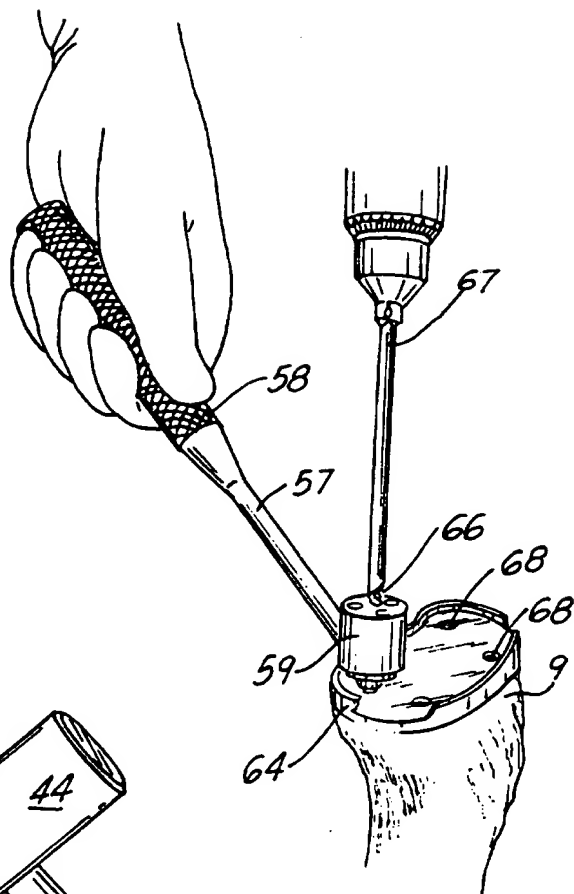


FIG. 12

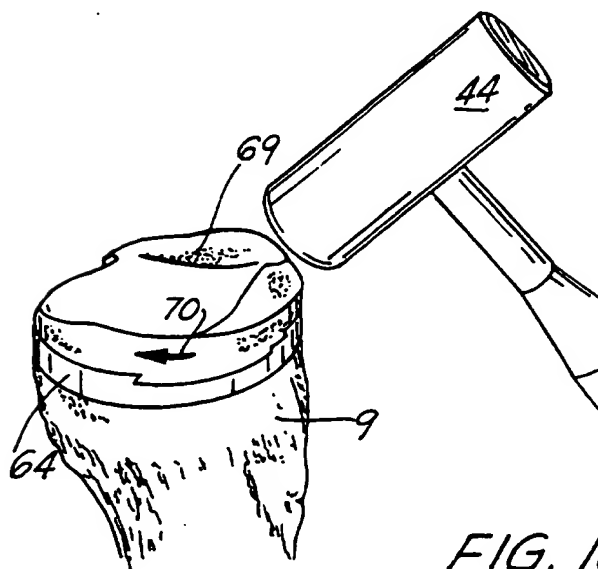


FIG. 13

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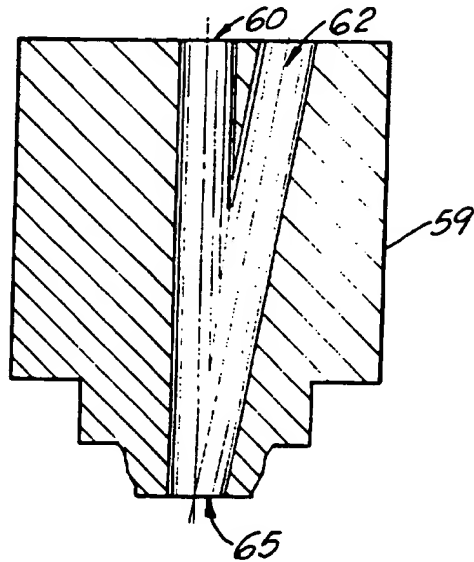


FIG. 14

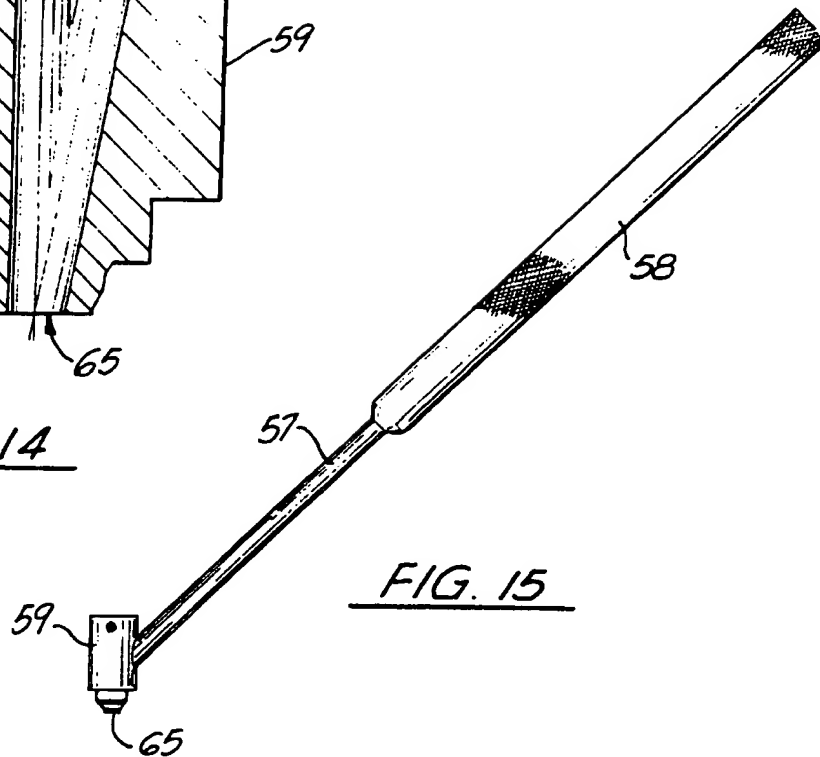


FIG. 15

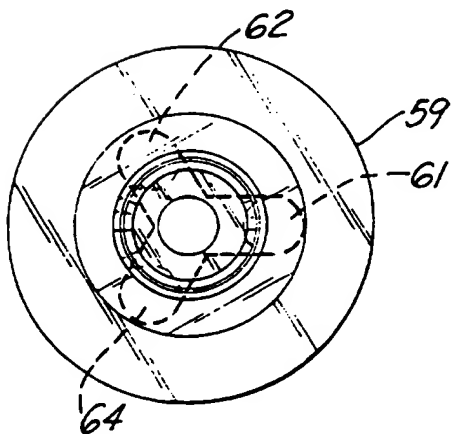


FIG. 16

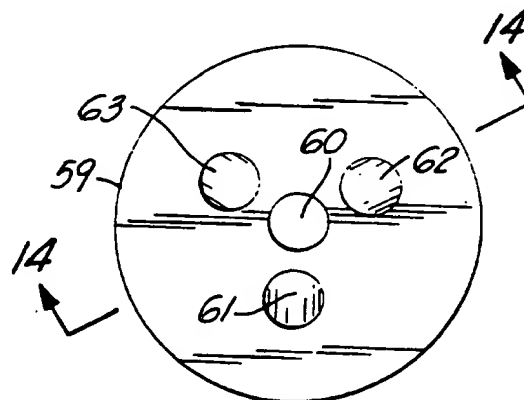


FIG. 17

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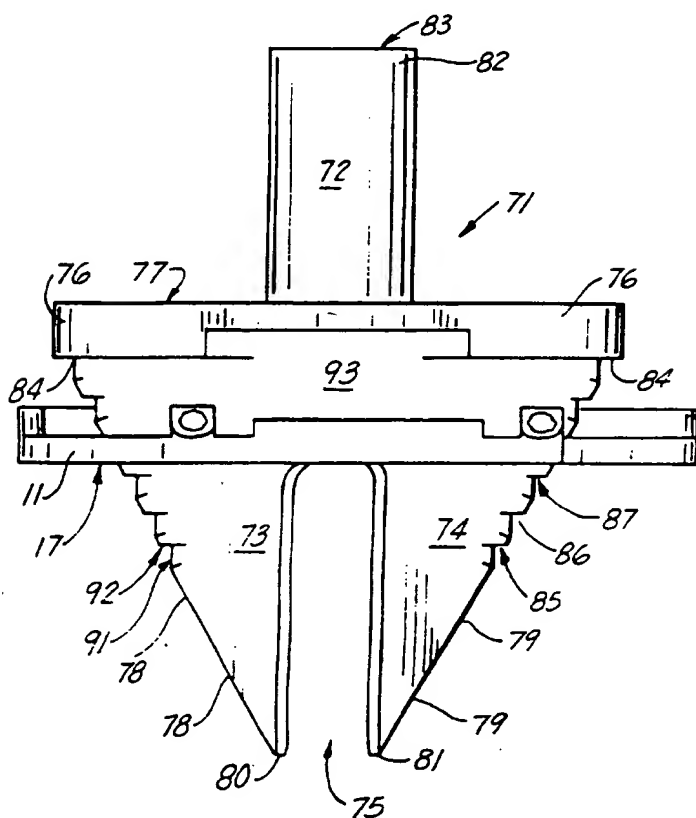


FIG. 18

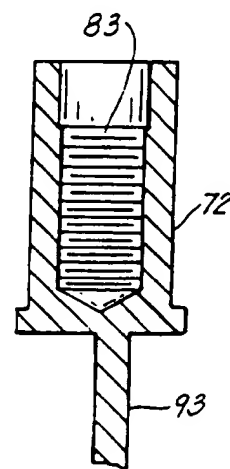


FIG. 21

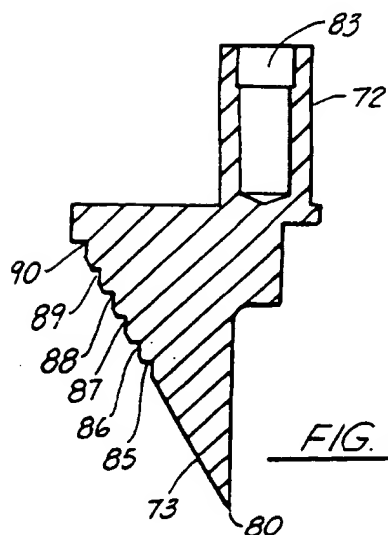


FIG. 20

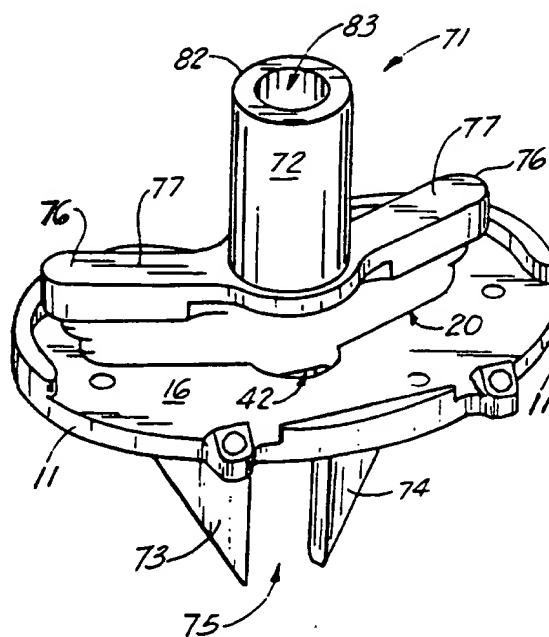


FIG. 19

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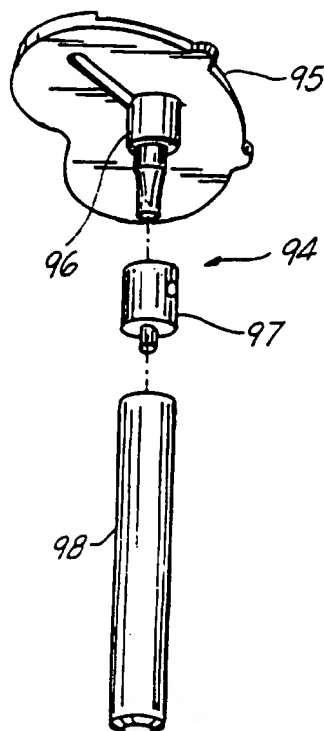


FIG. 22

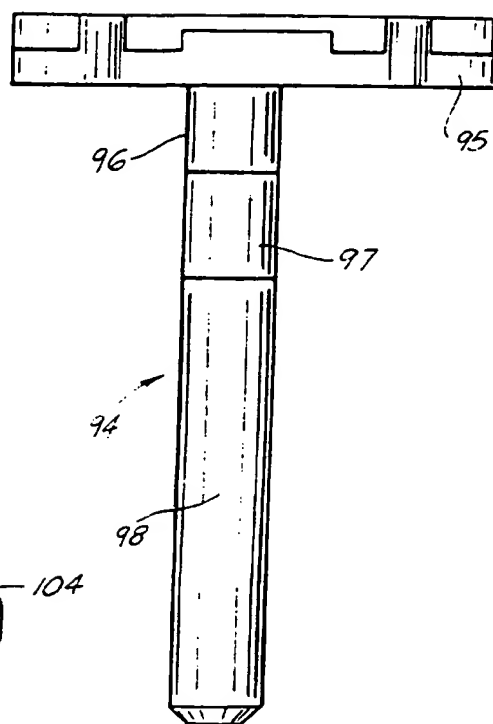


FIG. 23

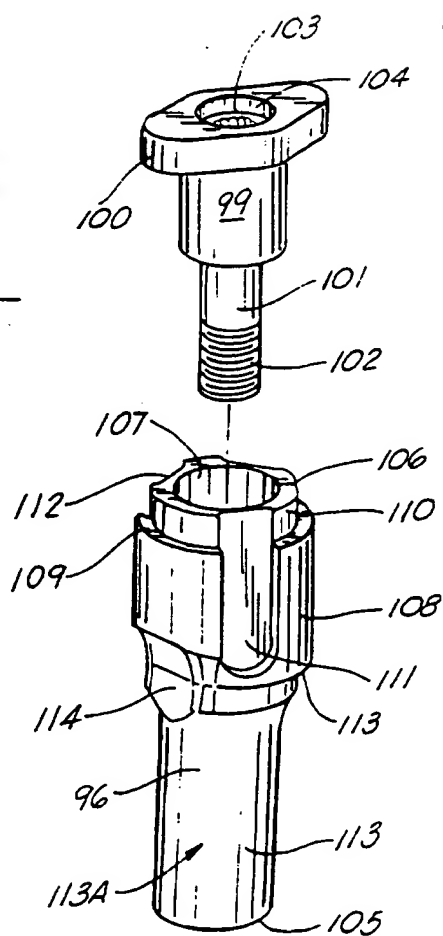


FIG. 24

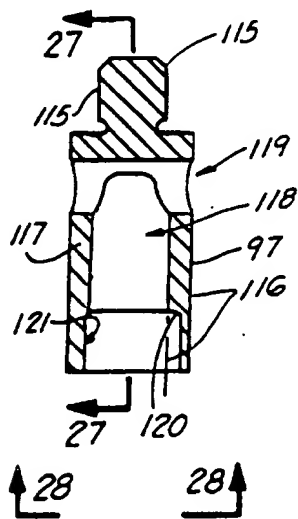


FIG. 25

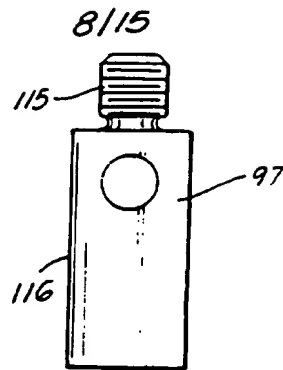


FIG. 26

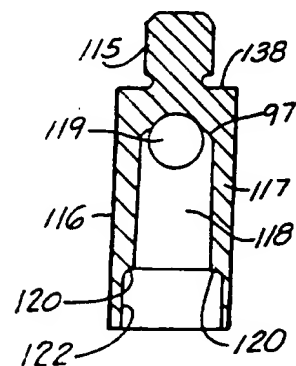


FIG. 27

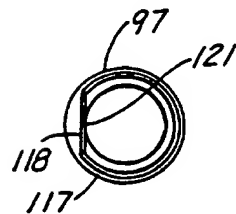


FIG. 28

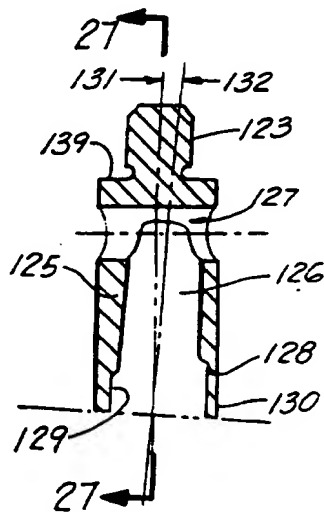


FIG. 29

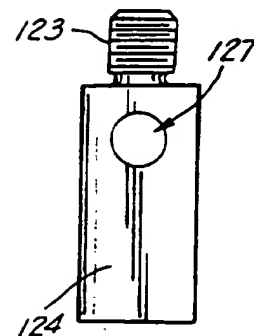


FIG. 30

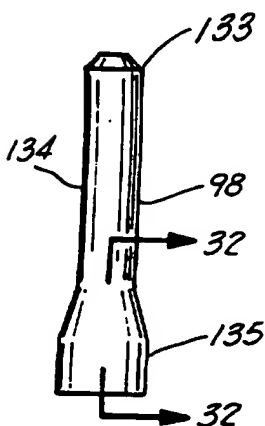


FIG. 31

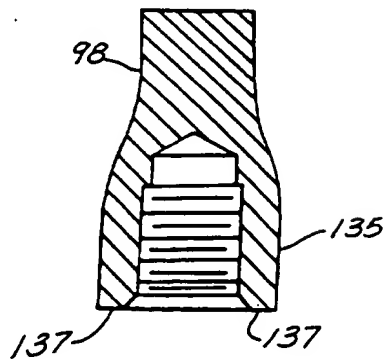


FIG. 32

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FIG. 33

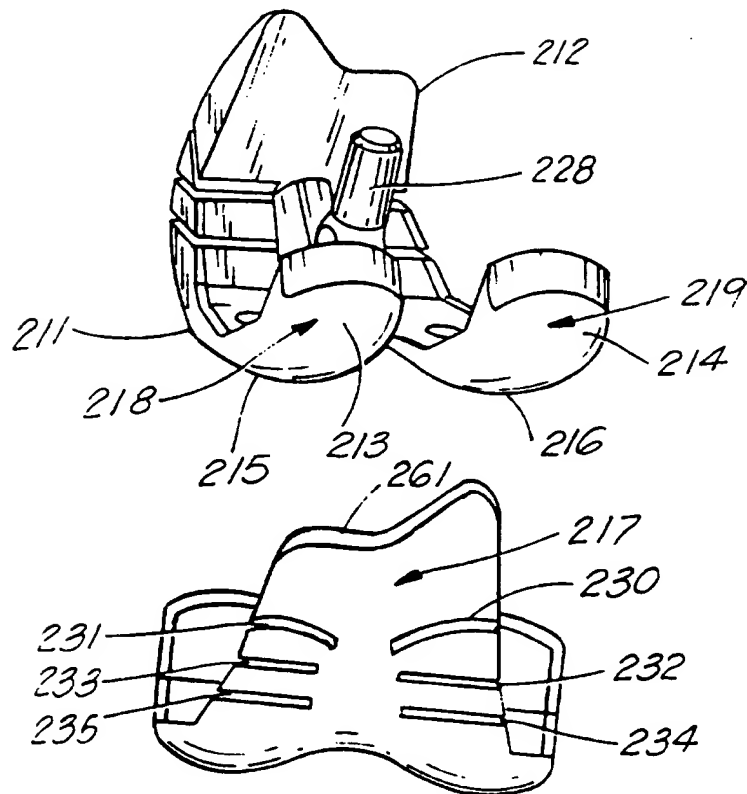


FIG. 34

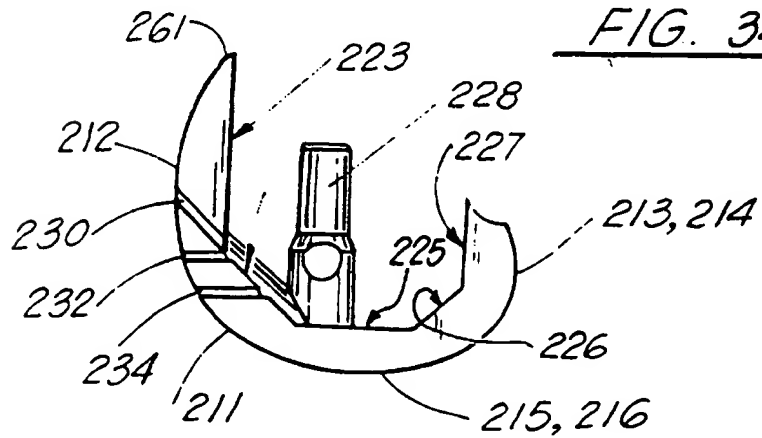


FIG. 35

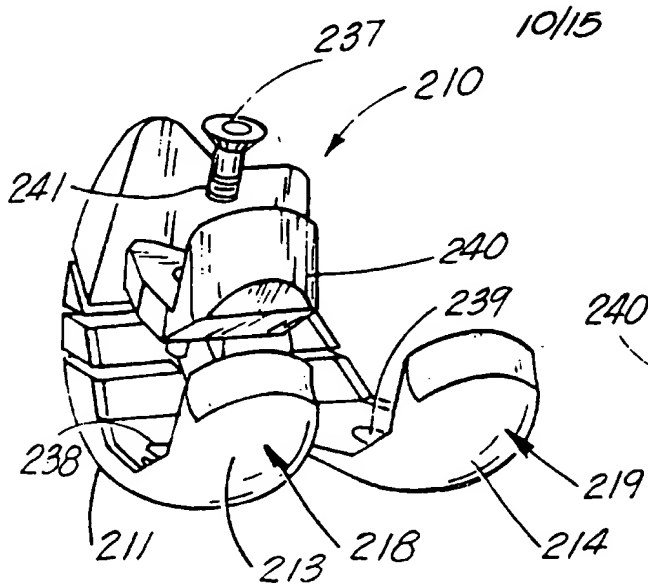


FIG. 36

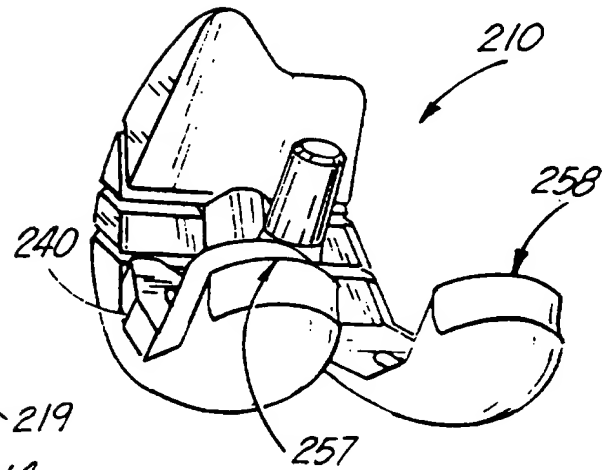


FIG. 37

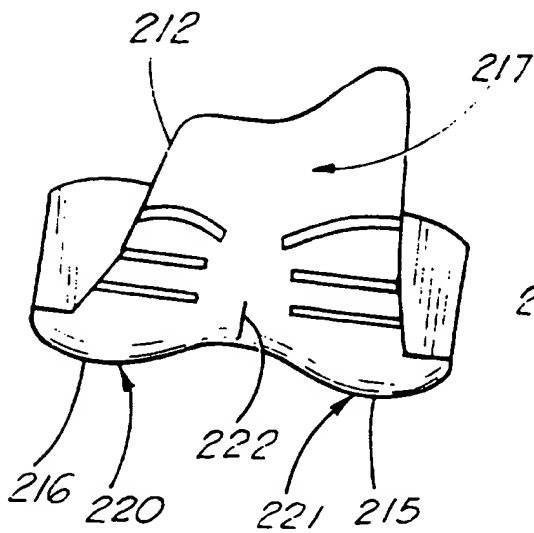


FIG. 38

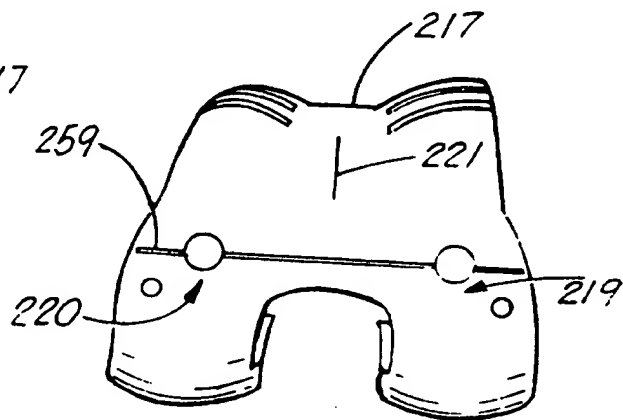


FIG. 39

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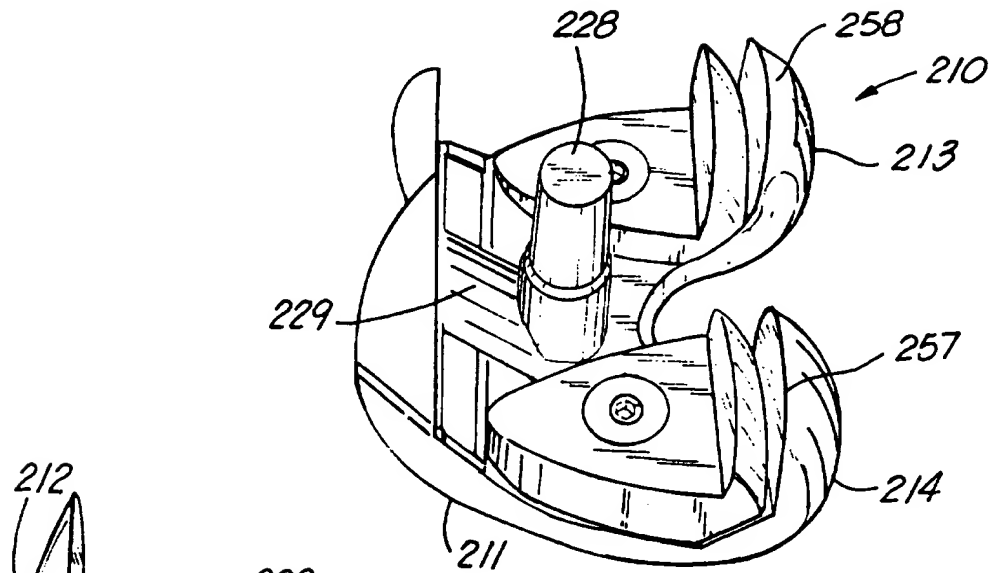


FIG. 40

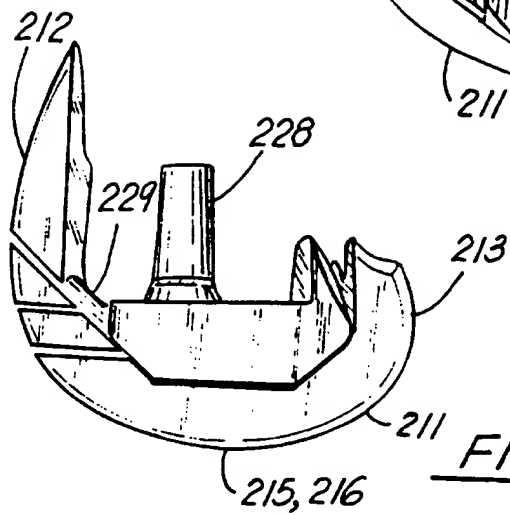


FIG. 41

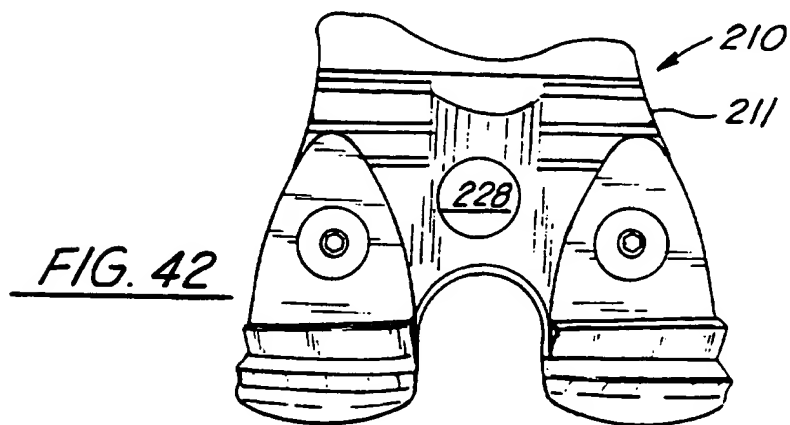
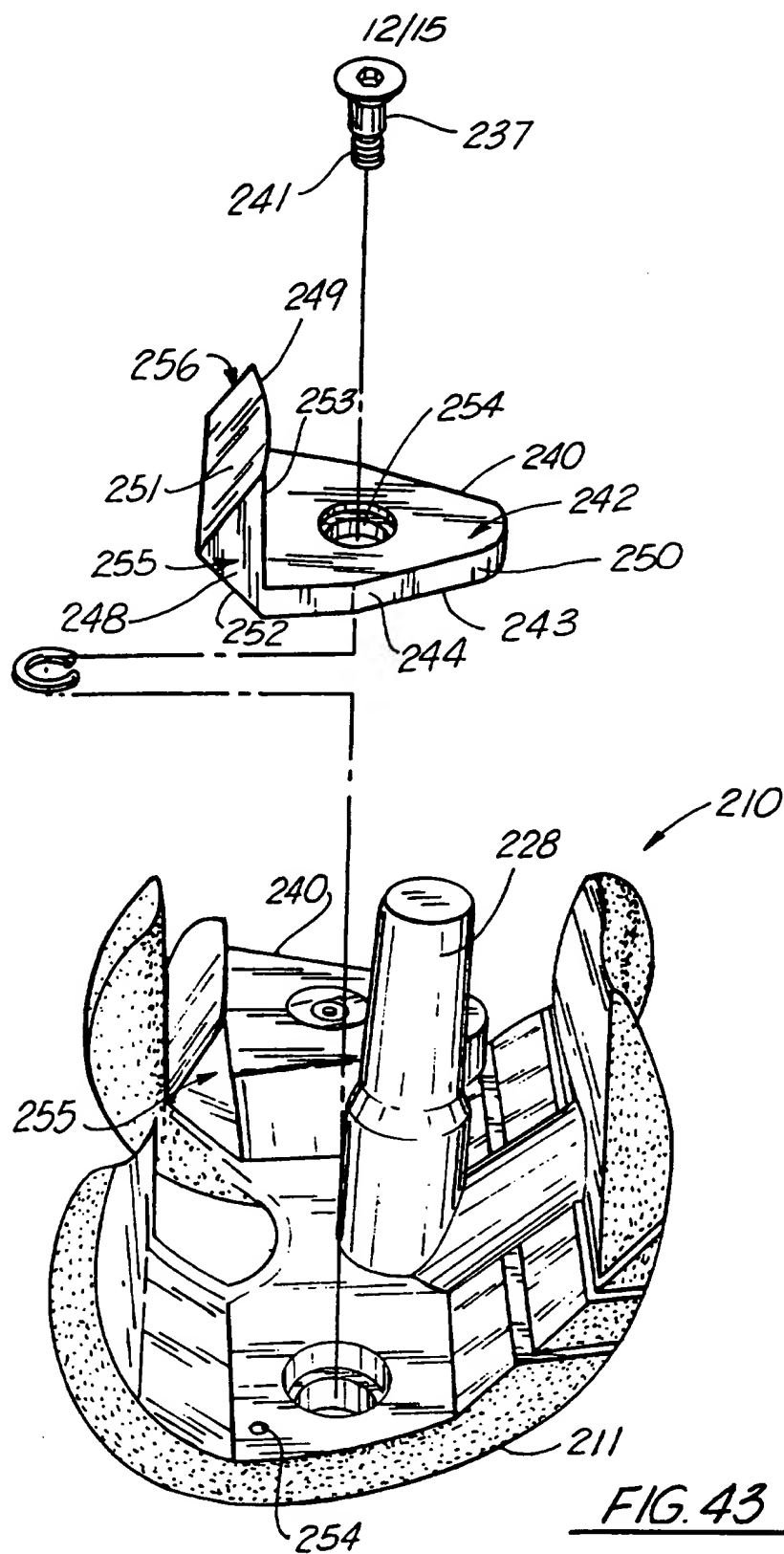
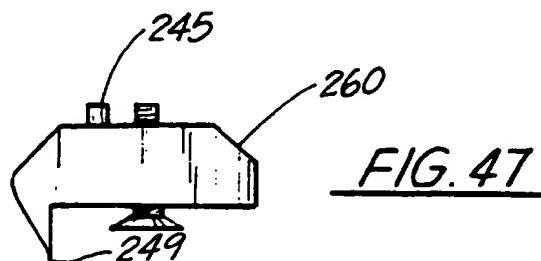
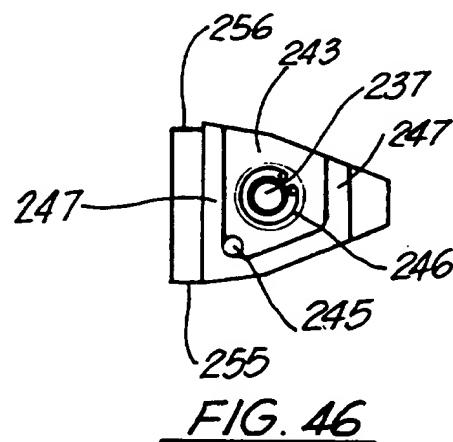
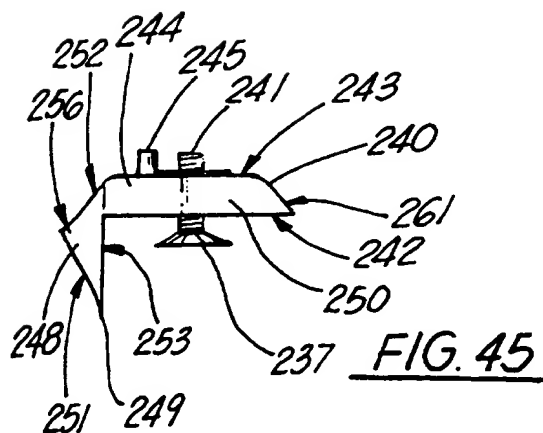
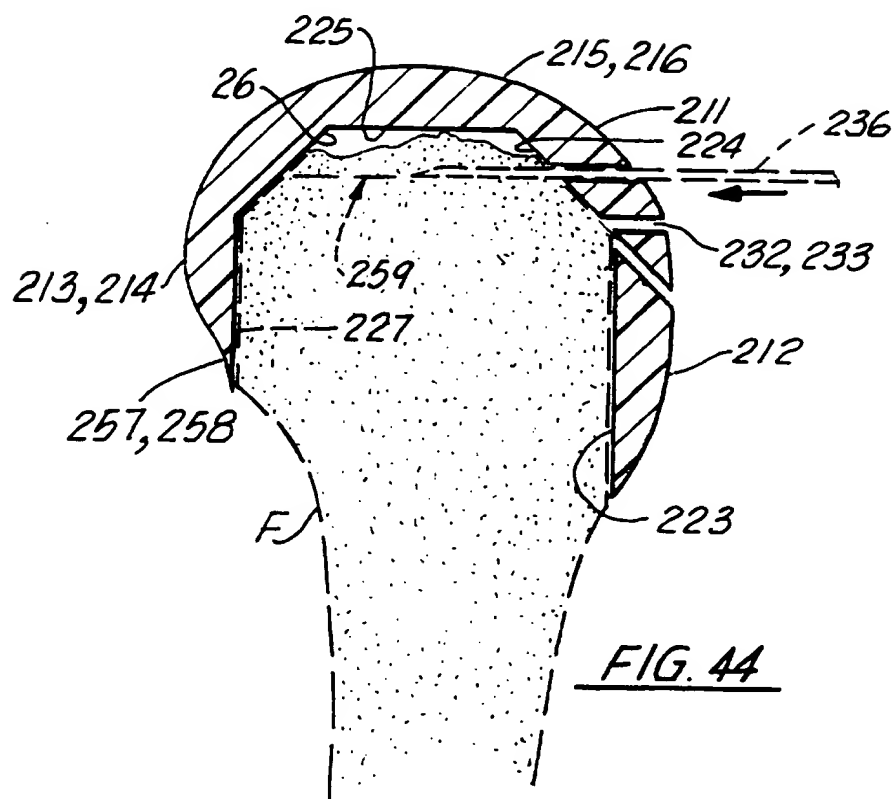


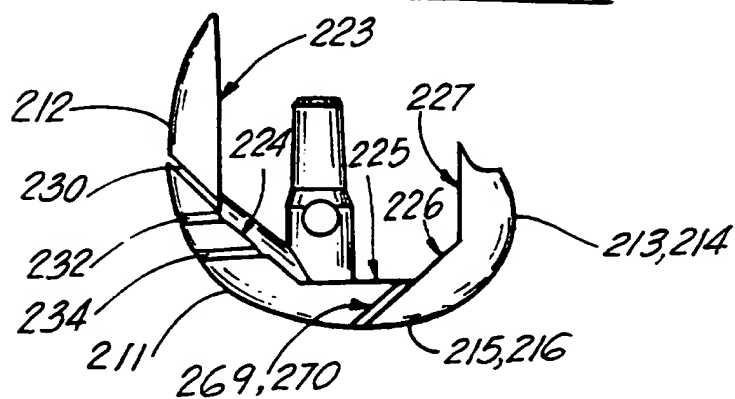
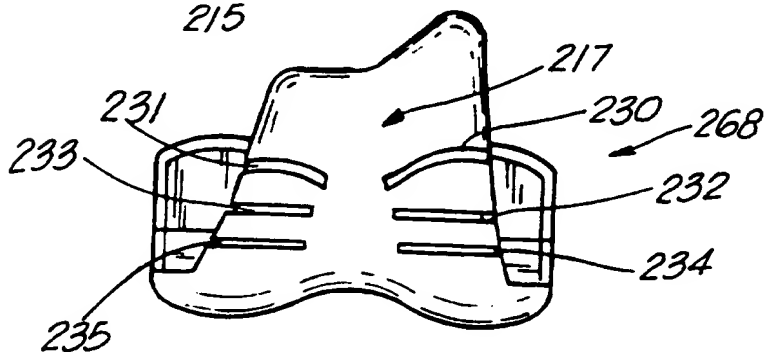
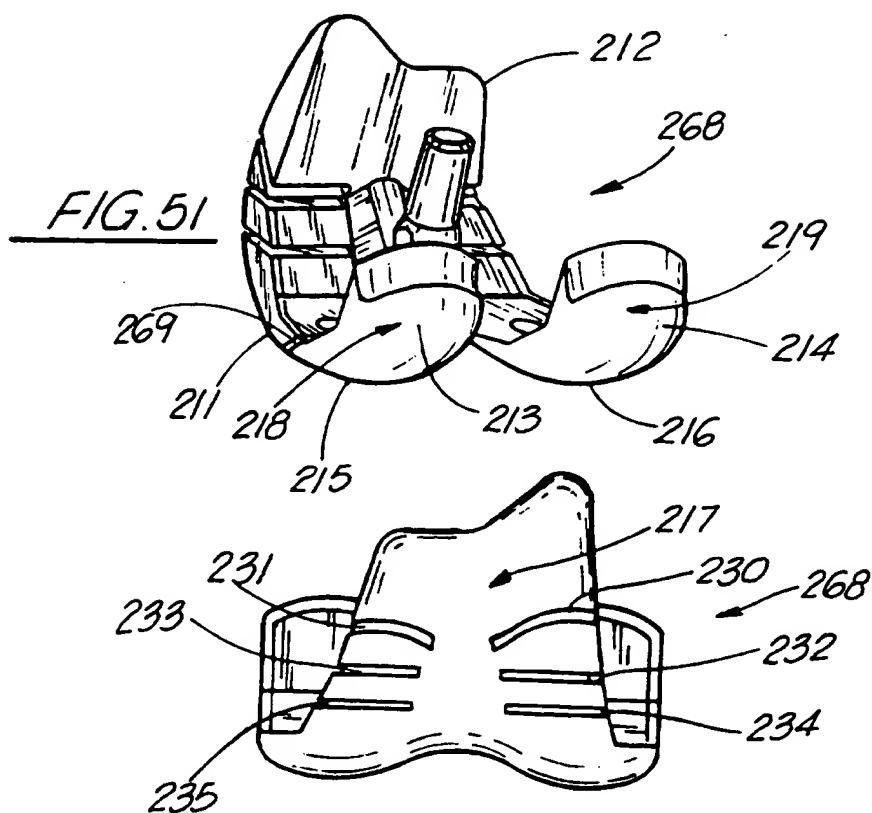
FIG. 42



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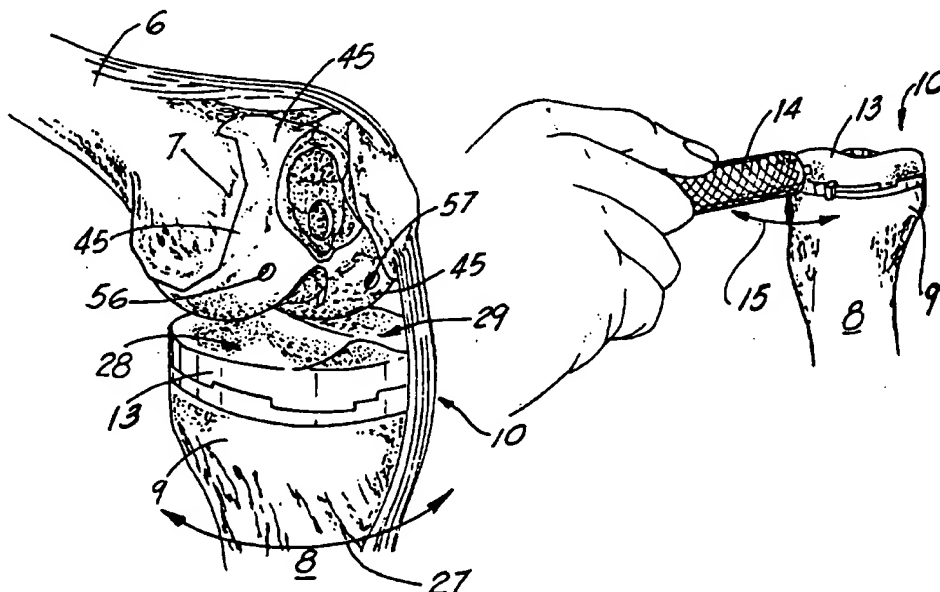




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁶ : A61F 2/38</p>	<p>A3</p>	<p>(11) International Publication Number: WO 96/25123</p> <p>(43) International Publication Date: 22 August 1996 (22.08.96)</p>
<p>(21) International Application Number: PCT/US96/02127</p> <p>(22) International Filing Date: 15 February 1996 (15.02.96)</p> <p>(30) Priority Data: 08/389,100 15 February 1995 (15.02.95) US</p> <p>(71) Applicant: SMITH & NEPHEW RICHARDS INC. [US/US]; 1450 Brooks Road, Memphis, TN 38116 (US).</p> <p>(72) Inventors: CARLS, Thomas, A.; 1736 Carruthers Place, Memphis, TN 38112 (US). JOHNSON, Chris, E.; 5030 Woodlark Avenue, Memphis, TN 38117 (US). STEELE, John; Suite 2303, 1050 South Blackhawk, Aurora, CO 80012 (US). VENDRELY, Tim; 2234 Brewer's Landing, Memphis, TN 38104 (US). WHITESIDE, Leo, A.; 3165 McKelvey Road, Bridgeton, MO 63044 (US). NARAGHIAN, Khosrow; 3426 Castleman, Memphis, TN 38118 (US).</p> <p>(74) Agents: KRIEGER, Paul, E. et al.; Pravel, Hewitt, Kimball & Krieger, P.C., 10th floor, 1177 West Loop South, Houston, TX 77027-9095 (US).</p>		<p>(81) Designated States: AU, CA, CN, JP, KR, SG, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p> <p>(88) Date of publication of the international search report: 26 September 1996 (26.09.96)</p>

(54) Title: TRIAL KNEE PROSTHESIS AND BONE PREPARATION SYSTEM



(57) Abstract

A trial knee prosthesis suitable for use in knee joint replacement surgery and for revising a previously implanted total knee implant is disclosed. The trial knee prosthesis comprises at least a trial tibial prosthesis (10), a trial femoral prosthesis (45), and includes a handle portion (14) for rotating the tibial trial prosthesis (10) about its stem (12). There is also provided a method for implanting a femoral knee prosthesis and a tibial knee prosthesis, and instruments for surgically implanting the femoral and tibial prosthesis components using the trial knee as disclosed.

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INTERNATIONAL SEARCH REPORT

 International application No.
 PCT/US96/02127

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/38

US CL :623/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/88; 623/20

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 5,194,066 (VAN ZILE) 16 March 1993, see entire document.	1 ----- 2-6
A	US, A, 5,194,066 (VAN ZILE) 16 March 1993, see entire document.	1 ----- 2-6
Y	US, A, 5,007,933 (SIDEBOTHAM ET AL.) 16 April 1991, see column 2 line 68 to column 3 line 2, and column 3 lines 11-25.	3
Y	US, A, 5,080,676 (MAY) 14 January 1992, see entire document.	4, 5

☒ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
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P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 22 JULY 1996	Date of mailing of the international search report 06 AUG 1996
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3590	Authorized officer <i>Randy Shay</i> RANDY SHAY Telephone No. (703) 308-2907

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US96/02127

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 5,019,103 (VAN ZILE ET AL.) 28 May 1991, see entire document.	6
X	US, A, 5,342,367 (FERRANTE ET AL.) 30 August 1994, See Abstract	9
Y	US, A, 4,950,298 (GUSTILO ET AL.) 21 August 1990, see entire document.	6
X	US, A, 5,342,367 (FERRANTE ET AL.) 30 August 1994, see Abstract.	9
A	US, A, 4,948,769 (SHAW) 03 July 1990, see entire document.	10, 11
Y, P	US, A, 5,489,311 (CIPOLLETTI) 06 February 1996, see entire document.	3-5
X	US, A, 5,326,359 (OUDARD) 05 July 1994, see entire document.	1
Y		2

INTERNATIONAL SEARCH REPORTInternational application No.
PCT/US96/02127**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/02127

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-8, drawn to a trial knee prosthesis.

Group II, claim 9, drawn to a tibial cutting instrument.

Group III, claims 10 and 11, drawn to a method of implanting a femoral and tibial knee prosthesis.

Groups I-III, the inventions listed in these groups do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I and II, the trial knee prosthesis of Group I and the tibial cutting instrument of Group II are separate devices which are unrelated to one another and have no common special technical feature.

Groups I and III do not share a special technical feature because the trial knee prosthesis sets forth neither an instrument or level engaging the tibial trial prosthesis, nor the tibial trial prosthesis being made out of a plurality of trays, stems, and inserts, which are the special technical features set forth in the method of Group III.

Groups II and III share no special technical feature because the cutting block means of Group II could be used in any number of types of surgeries, and the method implanting of Group III does not require the use of a cutting block means.